# EXHIBIT 14

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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|---|---|
| ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,<br><br>Plaintiffs,<br><br>v.<br><br>MODERNA, INC. and MODERNATX, INC.,<br><br>Defendants. | C.A. No. 22-252-MSG<br><br>**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY** |
| MODERNA, INC. and MODERNATX, INC.,<br><br>Counterclaim-Plaintiffs,<br><br>v.<br><br>ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,<br><br>Counterclaim-Defendants. | |

**DECLARATION OF PROFESSOR STEPHEN BYRN**

1. I, Professor Stephen Byrn, hereby declare as follows:

## I. INTRODUCTION

2. I am the Charles B. Jordan Professor of Medicinal Chemistry at Purdue University.

3. I have been retained by Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") in connection with the above-captioned lawsuit.

## II. BACKGROUND AND ASSIGNMENT

### A. The Suit

4. I have been advised by counsel for Moderna that Arbutus Biopharma Corp. and Genevant Sciences GmbH (collectively, "Plaintiffs") have asserted patents including U.S. Patent Nos. 8,058,069 (the "'069 Patent"), 8,492,359 (the "'359 Patent"), 8,822,668 (the "'668 Patent"),

9,364,435 (the "'435 Patent"), and 11,141,378 (the "'378 Patent") (collectively, the "Molar Ratio Patents") against Moderna. I have reviewed and analyzed the Molar Ratio Patents in connection with the opinions I express herein.

**B. Moderna's COVID-19 Vaccine**

5. Moderna's COVID-19 Vaccine, "mRNA-1273," is an FDA-approved drug product.[1] mRNA-1273 contains four lipids: SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC].[2]

**C. The Discovery Dispute**

6. I understand that Plaintiffs have requested drug product samples from all batches of drug product of Moderna's COVID-19 Vaccine, and specifically samples of drug product that contain 100 milligrams of lipid content per batch.

7. I have been advised by counsel that Moderna assigns "part numbers" to differentiate between formulations and processes used to make the drug product. For example, Moderna's drug product with part number [redacted] is manufactured as a [redacted] mL vial with a specification that requires lipid content of [redacted] MRNA-GEN-00456568 (Exhibit #A). One drug product vial of part number [redacted] would comprise [redacted] mg total lipid content.

8. I have been further advised by counsel for Moderna that, in response to Plaintiffs' sample request, Moderna has offered to produce 3 drug product samples for each part number that

[1] https://purplebooksearch.fda.gov/productdetails?query=125752.
[2] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f96b315c-fa57-4876-a7e5-a9b584d8e6e6

has been manufactured in the U.S.[3] and has objected to the production of the volume of samples requested by Plaintiffs on the grounds of relevance and disproportionality to the needs of the case.

9. I have been further advised by counsel for Moderna that Plaintiffs have filed an application to the Court in this case seeking an order compelling Moderna to produce samples from all batches of drug product of Moderna's COVID-19 Vaccine in response to Plaintiffs' RFP seeking "50 vials of the Accused Product from each lot referenced in Biologics License Application 125752 or that has otherwise been manufactured by or on behalf of Moderna." I understand that Plaintiffs have requested sufficient vials to comprise "100 mg of lipid" for each lot.

**D. Assignment**

10. I have been asked by counsel for Moderna to consider (1) whether "100 mg of lipid" for each batch is necessary to conduct testing for lipid content (2) whether Plaintiffs' justification that they need samples in order to determine the lipid content in individual LNPs is scientifically sound.

11. To answer these questions, I have considered the materials identified herein, and rely on my education, professional training, and expertise in medicinal chemistry as well as my general knowledge of chemistry, which I have developed in over 50 years of experience as a professor of medicinal chemistry.

12. I am being compensated for my time spent working on this matter at a rate of $850 per hour. I have no financial interest in the outcome of this case.

[3] I have been informed that Moderna transitioned from drug product vials to single-dose syringes and that for such batches Moderna would provide an equivalent number of syringe samples.

## III. PROFESSIONAL BACKGROUND & TESTIMONY

13. I received a Ph.D. in Chemistry from the University of Illinois in 1970 and was a post-doctoral fellow at UCLA from 1970 to 1972. In 1972, I became a professor in the Medicinal Chemistry and Pharmacognosy Department at Purdue University. I was Head of the Department of Medicinal Chemistry and Pharmacognosy at Purdue University in the School of Pharmacy and Pharmaceutical Sciences from 1988-1994. I was the Director of the Center for AIDS Research at Purdue form 1988 until 1998, and I was the Head of the Department of Industrial and Physical Pharmacy from 1994 to 2009. I became the Charles B. Jordan Professor of Medicinal Chemistry in 1992.

14. I am an author of over 225 peer-reviewed publications in technical journals on topics relating to solid-state chemistry, analysis, formulation, X-ray crystallography, stability, medicinal chemistry, chemistry, and the like. I am also co-author of the three leading books in the field of solid-state chemistry of pharmaceuticals. My most recent book was published by Wiley in 2017 and is entitled "Solid State Properties of Pharmaceutical Materials." Under my supervision, over 50 students and post-doctoral associates have published numerous papers and theses on many different compounds and formulations.

15. I have taught numerous courses as outlined in my Curriculum Vitae, attached as Exhibit B. At Purdue I co-authored a book entitled Quantitative Pharmaceutical Chemistry and lectured on HPLC. I have continued to lecture and work with HPLC since then. I have also taught at the federal Food and Drug Administration and have given I have also given over 270 invited lectures and symposium talks and presentations on solid-state chemistry, analysis, polymorphs, and similar topics.

16. I have used a wide range of analytical methods to characterize pharmaceuticals including HPLC, X-ray diffraction, NMR spectroscopy, environmental scanning electron microscopy, differential scanning calorimetry, thermal gravimetric analysis, IR spectroscopy, Raman spectroscopy, moisture sorption analysis, thermal microscopy, and dissolution.

17. I am the past Chair of the Pharmaceutical Sciences Advisory Committee at the FDA. The role of that Committee is to advise the FDA on polymorphism issues, biopharmaceutical issues, as well as general chemical manufacturing control issues, including formulation, dissolution, and hydrates. I am the former Chair of the Drug Substances Technical Committee of the Product Quality Research Institute (PQRI) where, to improve drug quality, we discussed three main areas: (1) specifications, (2) particle size, and (3) chemical impurities.

18. I am also past Chair of the Chemistry 5 Expert Committee at the USP (United States Pharmacopeia), and a past member of the Council of Experts at the USP. As part of my work on the Chemistry 5 Committee, I advised on over 500 monographs of the USP many of which included HPLC analyses.

19. In my laboratory, we are currently making lipid nanoparticles utilizing cationic lipids to encapsulate small molecule drugs. We routinely utilize HPLC and mass spectrometry to analyze these lipid nanoparticles.

20. My prior testimony is attached in Exhibit #C.

## IV. SUMMARY OF OPINIONS AND CONCLUSIONS

21. Based on my review of the materials cited in this declaration, it is my opinion that Moderna's use of an HPLC/UHPLC procedure to measure lipid content of each batch of its COVID-19 vaccine is reliable, standard method to determine lipid content. Genevant and the named inventors similarly use an HPLC/UHPLC method to measure lipid content.

22. I am not aware of any method for determining the lipid content of an isolated single LNP in Moderna's COVID-19 vaccine, let alone a method that would generate reliable or scientifically sound results.

23. It is also my opinion that Plaintiffs' request for 100 mg of lipid for each drug product batch is excessive and far more than what is needed to measure lipid content. I am not aware of any analytical techniques for determining lipid content that would require such large amounts of sample.

24. It is also my opinion that 3 drug product samples for each part number is more than an adequate amount of lipid for Plaintiffs to analyze lipid content.

## V. OPINIONS

### A. Scientific Background Information

#### 1. Lipid Nanoparticles

25. Lipid nanoparticles ("LNPs") are drug delivery vehicles comprising lipids—fatty compounds that are generally insoluble in water. The LNPs at issue here comprise four separate lipid components: a PEG lipid, cholesterol, a phospholipid, and an ionizable (referred to here as a cationic) lipid.

26. LNPs vary in size but are generally around 50-150 nanometers, which is thousands of times smaller than a grain of sand.

#### 2. Analytical Methods

27. Various analytical chemistry techniques are referred to in this declaration and in the case materials I have considered for purposes of my analysis. These analytical chemistry techniques include HPLC, UHPLC, and mass spectrometry among others.

28. I have been advised by counsel for Moderna that Plaintiffs have not identified what analytical method for lipid quantification that they will rely on in this case, if any, and have not identified any method that justifies the amount and quantity of samples they are seeking.

**a. HPLC and UHPLC**

29. High performance liquid chromatography ("HPLC") and ultrahigh performance liquid chromatography ("UHPLC" or "UPLC") are techniques used to separate compounds in mixtures while in solution. HPLC and UHPLC/UPLC operate on the same principles. For both, separations occur on a stationary phase (usually silica or chemically derivatized silica) that is packed into a column. Solvent (called the mobile phase) is pumped through the column, and a compound mixture is injected into the flowing solvent and onto the column. Due to differences in interactions between the stationary phase and the compounds in the mixture such as adsorption, the compound mixture can be separated as it flows through the column such that each compound elutes (is washed out or removed) at a different time.

30. Using standard equipment and methodology, you cannot inject 100 mg of lipids into an HPLC/UHPLC column.

31. HPLC/UHPLC is generally considered a standard method for measuring lipid content.

32. In Plaintiffs' expert David H. Thompson's *Markman* declaration concerning the Molar Ratio Patents, he cites articles showing that HPLC is a preferred method for measuring lipid content. *See* D.I 181, J.A. 29 (Thompson Decl.) at ¶ 56 *citing* P. Tam et al., *Stabilized plasmid-lipid particles for systemic gene therapy*, Gene Therapy, vol. 7, pp. 1867-74 (2000) ("Tam 2000") and J. Heyes et al., *Synthesis and characterization of novel poly(ethylene glycol)-lipid conjugates*

*suitable for use in drug delivery*, Journal of Controlled Release, vol. 112, pp. 280-90 (2006) ("Heyes 2006").

33. HPLC/UHPLC cannot be used to determine the lipid content of an isolated single LNP.

**b. Mass spectrometry**

34. Liquid chromatography-mass spectrometry and LC-tandem mass spectrometry involve the interfacing of HPLC or UHPLC to a mass spectrometer or a mass spectrometer capable of analyzing the sample using the MS/MS technique. Mass spectrometers convert molecules to gas phase ions that are then separated and analyzed in an electromagnetic field according to their mass-to-charge properties. High resolution mass spectrometers can analyze ions with such accuracy that the elemental compositions of the ions can be determined. Tandem mass spectrometers provide a second dimension of ion characterization by selecting a specific precursor ion, fragmenting it (usually using a gas phase process called collision-induced dissociation) and then recording all or specific fragment ions that provide structural information about the precursor ion.

35. Mass spectrometry cannot be used to determine the lipid content of an isolated single LNP.

**B. Molar Ratio Patents**

36. The Molar Ratio Patents do not refer to any analytical method for measuring lipid content in the specification or the claims.

37. Dr. Kieu Lam, named co-inventor of the Molar Ratio Patents, used HPLC to analyze lipid content, [redacted]

[redacted]

**C. Genevant Uses HPLC/UHPLC to Measure Lipid Content**

38. I understand that Genevant has stated in a discovery response that "lipid content and/or lipid molar ratio of a lipid composition may be determined using liquid chromatography, such as high-performance liquid chromatography ("HPLC") or reverse phase HPLC ("RP-HPLC"), coupled to a suitable detector, such as an evaporative light scattering detector ("ELSD") or a charged aerosol detector ("CAD"). Other methods such as mass spectrometry may also be used." Genevant Responses to Moderna's Third Set of Interrogatories at 6-7 (Interrogatory No. 13).

39. Genevant developed a method using [redacted]

40. [redacted]

**D.** [redacted]

[4] 1 milligram (mg) is 1000 micrograms (µg).

43. [redacted]

44. [redacted]

45. [redacted]

46. [redacted]

47. [redacted]

**E. Other Analytical Methods**

48. I am not aware of any procedure for determining lipid content of an LNP that would require more than 100 µg of lipid content.

**F. Lipid Content Testing for Individual LNPs**

49. There are likely millions if not trillions of individual LNPs in a given dose of Moderna's COVID-19 vaccine. As stated above, LNPs vary in size but are generally around 50-150 nanometers, which is thousands of times smaller than a grain of sand.

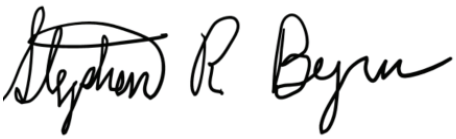
50. Plaintiffs' Motion indicates that they seek to perform testing to measure the lipid content in individual lipid particles ("that testing measures the *aggregate* concentrations of lipids in a batch; it does not measure the lipid ratio of LNPs amongst the trillions of particles in each batch."). Applying Plaintiffs' interpretation of the Molar Ratio Patent claims, I am not aware of any method for isolating a single LNP. Similarly, I am not aware of any method for determining the lipid content of an isolated single LNP. As stated above, HPLC/UHPLC cannot be used to determine the lipid content of an isolated single LNP.

51. The Molar Ratio Patents do not describe any method for isolating a single LNP or any method for determining the lipid content of an isolated single LNP. As stated above at ¶ 39, the named inventors' notebooks that Plaintiffs have identified as underlying those patents show that the inventors used HPLC and measured aggregate concentrations (though those measurements and the method are not reported in the Molar Ratio Patents).

* * *

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed on this January 5, 2024



Stephen Byrn

# EXHIBIT A

# EXHIBIT B

# CURRICULUM VITAE - DR. STEPHEN R. BYRN

**Professional Title:** Charles B. Jordan Professor of Medicinal Chemistry; School of Pharmacy and Pharmaceutical Sciences, Department of Industrial and Physical Pharmacy, Purdue University, West Lafayette, Indiana 47907

**Home Address:** 824 Barlow Street, West Lafayette, Indiana 47906

**Marital Status:** Married, ten children

**Education:** DePauw University, Greencastle, Indiana, B.A.,
1962-1966, Chemistry

University of Illinois, Urbana, Illinois, Ph.D.,
1966-1970, Organic and Physical Chemistry

University of California, Los Angeles, California, Postdoctoral, 1970-1972, Physical Chemistry

**Professional Experience:** Assistant Professor of Medicinal Chemistry, Department of Medicinal Chemistry and Pharmacognosy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana, July 1, 1972 to June 30, 1976

Associate Professor of Medicinal Chemistry, Department of Medicinal Chemistry and Pharmacognosy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana, July 1, 1976 to June 30, 1981

Professor of Medicinal Chemistry, Department of Medicinal Chemistry and Pharmacognosy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana, July 1, 1981 to present

Associate Department Head of Medicinal Chemistry, Department of Medicinal Chemistry and Pharmacognosy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana, 1979 to 1988

Assistant Dean of the Graduate School, Purdue University, West Lafayette, Indiana, 1984 to 1988

Head, Department of Medicinal Chemistry and Pharmacognosy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana, l988 to 1994

Founder and Director, Purdue University Center for AIDS Research, September 30, l988 to March 1, 1998

Head, Department of Industrial and Physical Pharmacy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana, September 1, 1994 to June 30, 2009

Charles B. Jordan Professor of Medicinal Chemistry, 1992 to present.

Co-Director, Center for Biotechnology Innovation and Regulatory Science, Discovery Park and Agricultural and Biochemical Engineering Department, 2014-present

Director, NIPTE Center of Excellence for Abuse Deterrent Formulations, March, 2017-present

**Memberships:**

Phi Eta Sigma, Rho Chi, Phi Lambda Upsilon, Phi Kappa Phi, Sigma Xi
American Chemical Society
American Crystallographic Association
American Association of Pharmaceutical Scientists

**Awards, Honors:**

Rector Scholar, DePauw University, 1962-1966
Sinclair Oil Company Fellow, University of Illinois, 1967-1968
National Science Foundation Graduate Fellow, University of Illinois, 1968-1971
National Institutes of Health Postdoctoral Fellow, University of California, 1971-1972
Elected Fellow, American Association of Pharmaceutical Scientists, 1989
Elected Member, United States Pharmacopeia Revision Committee, 1990-1995 & 1995-2000 & 2000-2005. Council of Experts 2000-2005, Member of several subcommittees including chemistry, dissolution, excipients and PAT.
Purdue University Representative to the USP, 2000, 2005, 2010.
Alumni Citation, DePauw University, 1991
Thomas W. Binford Memorial Award for Outstanding Contributions to Entrepreneurial Development, World of Difference Award, State of Indiana, 2000
FDA Advisory Committee Service Award, October 31, 2001
AAPS Outstanding Paper Award, 2008, APQ Section (With L. Taylor)
Purdue University, Outstanding Faculty Commercialization Award, 2008-09
AAPS David Grant Research Achievement Award in Physical Pharmacy, 2009
Special Issue (September 2010) of the Journal of Pharmaceutical Sciences was dedicated to Stephen R. Byrn, based on his contributions to the field of solid state pharmaceutics.
FDA Honor Award. Stephen Byrn as Member of FDA/Kilimanjaro School of Pharmacy Regulatory Collaboration, 2013
AAPS Dale Wurster Award In Pharmaceutics, November 16, 2016.
LSAMP Faculty Mentor of the Year Award, Purdue University, 2018
Pharmaceutical Sciences Teacher of the Year Award, Purdue University, 2018
Purdue University Morrill Award, Most Outstanding Faculty Member, 2018
AAPS Pharmaceutical Global Health Award, November 2018

**Memberships, Editorial Boards and Major Committees:**

Journal of Pharmaceutical Sciences Editorial Advisory Board - 1994-present.
AAPS Pharm. Sci. Tech. Editorial Advisory Board – 2007 – present.
Pharmaceutics Editorial Advisory Board - 2009 – 2014
Journal of Validation Technology, Editorial Advisory board – 2010 – 2012
Crystal Growth and Design Editorial Advisory Board – 2002 to 2007
Journal of Drug Targeting, 1993-1995.
Journal of Pharmaceutical and Biomedical Analysis, 1998-2002
Pharmaceutical Sciences Advisory Committee, FDA 1997-2001, Chair 2000-2001
Controlled Substances Advisory Committee, State of Indiana 1982-1998 (Chair 1995-8)
Drug Substance Technical Committee, FDA-PQRI, 1997-present (Chair 1997-2001)
National Academies of Sciences, Engineering, and Medicine, Topical Pain Creams, March 1, 2019 - present

**Professional Service:**

American Chemical Society, Secretary-Treasurer, Vice-Chairman and Chairman Purdue Section, 1976-1982

Controlled Substances Advisory Committee, l982-1998, Secretary, 1987-1994, Chair, 1994-1998

American Society of Pharmacognosy, Program Committee, 1977

Symposium Organizer American Chemical Society, Division of Medicinal Chemistry, 1987

Organizer, First and Third Midwest Organic Solid State Chemistry Symposia, 1988 (University of Illinois), 1990 (Purdue University), 2005 (Purdue University, with Ken Morris). Co-organizer, 2016 (Purdue University)

Organizer of a Short Course, entitled "Polymorphs and Solvates of Drugs," 1988 (Bradford, England), 1990 (Purdue University), 1992 (Bradford, England)

Reviewer numerous journals including JACS, J. Org. Chem., Acc. Chem. Res., J. Pharm. Sci., Pharm. Res., Crystal Growth and Design

Chair, NIPTE Abuse Deterrent Center of Excellence 2017 - present

**University Committees:**

Athletic Affairs Committee, 1979-1984
Computer Center Policy Committee, 1983-1988
Commencement Committee, 1984-l989
Development Committee, 1991-2
Vision (Long Range Planning) Committee, 1993
University Promotions Committee 1995-1998.
Purdue University Faculty Senate 2007-2010 and 2012-2016.
Global Academic Committee, 2018-Present

**Departmental Committees:**

As Chair of two departments I have served on numerous departmental committees.

**Graduate School Committees:**

M.D.-Ph.D., 1984-1988
Area Committee, 1984-1988
Computer Committee, 1984-1988
Residency Review Committee, 1984-1988
David Ross Fellowship Committee, 1984

**Teaching Effort:**

Courses Taught – Pharmacy and Doctor of Pharmacy Curriculum

Pharmaceutical Solids, 1998-2001.

Regulatory Affairs, 1998-present.

MDCH 310 - Analytical Medicinal Chemistry, l972-1997

MDCH 418 - Computers in Pharmacy, l978-1988

IPPH 471 – Sterile Products – Instructor in Charge 2004-05, 2014

IPPH 363 – Industrial Pharmacy - 2008-2012 (Instructor in charge, 2010)

PHRM 898 – Dosage Forms I – Solid state, Tablets, Capsules – 2012-present, course coordinator 2017

PHRM 461 – Drug Discovery and Development II –Course coordinator or co-coordinator, 2014-present

Courses Taught - Graduate Curriculum

MDCH 614 - Advanced Medicinal Analysis, l972-1997

IPPH 590/587 - Pharmaceutical Solids 2004 – 2018

MDCH 698, 699 - Directed research for M.S. and Ph.D. graduate students and post-doctoral associates. 1972 - Present

IPPH 521– Drug Development 2004 - 2014

IPPH 522 – Good Regulatory Practices 2004 – 2014

IPPH 562 – Pharmaceutical Manufacturing 2010

PHRM 46100 – Drug Discovery and Development II, 2013-present

ABE 52100 – Drug Development 2015 - present

ABE 52200 – Good Regulatory Practices, 2015-present

IT 50800 - Quality and Productivity in Industry and Technology

IT 57100 Project Management in Industry and Technology

**Teaching Programs Co-Founded – MS Degree in Biotechnology Innovation and Regulatory Sciences in the US and Africa (Joint with Professor Kari Clase, Ph. D.) originally Program in Regulatory and Quality Compliance, cofounded jointly with M. Schmidt, Ph. D.:**

This new area of specialization in the Agricultural and Biochemical Engineering Department focuses on creating leaders in biotechnology innovation and regulatory science, especially relating to pharmaceuticals. The curricula also addresses topics of innovation and integrates emerging technologies.

The program consists of 10 courses and a special project for a total of 30 credit hours. The array of courses will provide:

- an understanding of all aspects of quality
- an understanding of biotechnology innovation and regulatory science
- in-depth knowledge related to biotechnology and pharma
- knowledge on how to lead and manage operations within the industry

The degree format is tailored to student needs:

- Traditional, on-campus degree program in West Lafayette
- Blended online and weekend program

- In Africa in collaboration with Kilimanjaro School of Pharmacy, Moshi, Tanzania and Nelson Mandela, African Institute of Science and Technology, Arusha, Tanzania

**Sustainable Medicines in Africa (Joint with Sr. Zita Ekeocha, M.S. and Professor Kari Clase)**

The sustainable medicine program in Africa is aimed at addressing the problem of lack of access to high quality medicines in Africa. This program consists of: (1) Master's degree in Biotechnology Innovation and Regulatory Science (Sr. Zita Ekeocha)); (2) an actual GMP-level pharmaceutical manufacturing facility (2008 – 2020), and (3) a quality medicines laboratory equipped with HPLCs. The educational programs are aimed at providing source of well-trained manufacturing scientists for pharmaceutical industry in Tanzania and Africa. The GMP-level facility and GMP courses are used to teach manufacturing under strict quality control. The GMP facility served as a model for other such facilities throughout Sub-Saharan Africa. The feasibility of establishing a sustainable medicine program in Tanzania is supported by the experience of the former Infusion Units Project in Tanzania, now known as Saint Luke Foundation (SLF). This program has manufactured and distributed infusion solutions throughout Tanzania since 1983. Additionally, the availability of trained personnel and a model facility will combat several current problems especially those related to counterfeited/poor quality medicines.

This Master's degree in Biotechnology Innovation and Regulatory Science is supported by Bill and Melinda Gates Foundation as an ANDi (African National Drug Innovation) Center for Pharmaceutical Manufacturing and Regulatory Training. This center is one of less than 50 centers in Africa.

**Graduate Students and Postdoctoral Associates:**

M.S. (thesis) - E. Kreutzer (1976), S. VanEss (1977), B. Stewart (1978), G. Migliaccio (1979), G. Gibson-Clay (1979), J. Gomes (1979), P. Hoyos (1982), L. Morales (1991), H. Tat (1998), R. Alajlouni

Ph.D. - G. Dolch (1976), M.D. Tsai (1978), R. Clay (1979), J. Gomes (1981), H. Martinez (1983), I. Lassalle (1984), P. Sutton (1984), P. Toren (1985), J. Chaber (l986), D. Kessler (l986), P. Hoyos (l986), E. Kolodziej (l986), D. Carlson (l989), C. Chan (1990), P. Saindon (1991), K. Ray (1992), N. Sipahimalani (1992), Wu-Po Ma (1993), D. Nugyen (1993), P. Toma (1993), G. Stephenson (1994), M. Wahle (1997), W. Xu (1997), T. Borchardt (1997), V. Joshi (1998), X. He (1999), R. Te (2000), X. Chen (2000), Y. Hu (2000), Zhihui Qui (2001); Hui Li (2002); T. Davis (2003), A Gupta (2005), Chen Mao (2007), Faraj Atassi (2007), EunHee Lee (2007), Yuerong Hu (With L. Taylor) (2008); Niraj Trasi (2011), Ziyang Su (2011); Sumana Penumetcha (2011); Xin Chen (2012); Y. Song (2015), H. Nie (2017); Salma Salem (2019)

Postdoctoral Associates - P.Y. Siew (1976), C.T. Lin (1980), P. Perrier (1981), J. Stowell (1984), B. Tobias (l988), C. Chan (1990), C. Cox (1990), Kin-shan Huang (1995), R. Schlam (1999); N. Poendaev (2001-2003), D. Smith (2003-2006), Eun Hee Lee (2007-2010), Salma Salem 2020 - present

Current Graduate Students - None

Current Senior Research Associate – Daniel Smith, Ph. D.

**Undergraduate Student Activities:**

Counselor for Pharmacy Students, 1978-1996.
Faculty Fellow (Shreve Hall & Hillenbrand Hall), 1982-1997.
Senior Faculty Fellow (Shreve Hall), 1986-1990.
Senior Faculty Fellow (Hillenbrand Hall) 1993-1995
Adopt a Student Program, College of Pharmacy, 2009-10

**Research Interests:**

**Solid State Chemistry of Drugs/Pharmaceutical Solids**

Investigators: S. Byrn, Amrinder Singh

The overall goal of our research is to develop the field of Solid State Chemistry of Drugs so that all of the principles and factors governing solid state chemistry are understood. This knowledge is then used to predict and analyze all behaviors of solids observed during the drug development process and in formulations. Thus, the solid state chemistry of drugs is being studied to improve knowledge of the factors which affect this chemistry and to develop new methods of studying these reactions. At present, our group is focusing solid state structure using PDF function analysis of data from Argonne National Laboratory, and stability. We are also interested solid state desolvation reactions, solid state decarboxylation reactions, solid-solid reactions, and solid state rearrangements. These studies are important in that they will lead to better understanding of the mechanism of drug degradation and eventually to new approaches to stabilizing drugs. By carrying out research on the solid state chemistry of drugs it is hoped that new approaches and ideas for drug analysis including solid state NMR spectroscopy and X-ray diffraction will be developed. In addition, this research is aimed at providing new insight into drug stability and at developing methods for predicting drug stability. Furthermore, approaches to the production via crystallization of the desired drug form are an important component of these studies.

**Processing and Manufacturing of Pharmaceuticals**

Investigators: S. Byrn

Approaches to understanding the molecular basis of pharmaceutical manufacturing are being developed. These approaches which include Raman mapping and EDS can in favorable cases provide information on the spatial location of all components in tablets and capsules. The effect of processing on the solid state chemistry of drugs and the stability of formulations is also being investigated. Particular emphasis is placed on the wet granulation and coating. Continuous manufacturing and manufacturing design are also being investigated especially for protease inhibitors and fixed dose combination drugs. The regulatory aspects of processing and manufacturing are also being emphasized.

**Analysis of Amorphous Pharmaceuticals**

Investigators: S. Byrn

The structure of amorphous pharmaceuticals is not known and poorly understood. Pair distribution functions derived from X-ray powder diffraction measurements made at Argonne National Laboratories Synchrotron as well as solid state NMR measurements along with more conventional studies can provide phase diagrams and information on the functional groups and atom-atom distances involved in drug-drug and drug –polymer interactions present in amorphous materials. These methods will lead to the establishment of a rational design method for amorphous compositions. This bottom-up design approach focuses on amorphous protease inhibitors since these are the most bioavailable compositions. This new method will determine structural details of amorphous compositions by providing atom-atom distances and other structural parameters. We will use the atomic distances, and other parameters determined, to predict properties of these compositions including stability (failure to crystallize), dissolution rate, and bioavailability. This method is particularly important since amorphous drugs are now being used to cure HCV and as potential treatments for a range of other viral diseases besides HIV.

**Abuse Deterrent Formulations of Opioids**

Investigators: Dan Smith

The goal of the abuser is to alter the opioid dosage from such that it provides a plasma concentration that is sufficient to induce euphoria. The abuse-deterrent dosage form is designed to minimize the feeling of euphoria when taken as prescribed by a patient, i.e. when using the medication as intended. However, a prescription drug abuser would try to modify the dosage form in a manner to increase the plasma concentration to a level that would induce euphoria. They can achieve this by increasing the rate of drug uptake. For example, they could crush a controlled release tablet, which would induce dose dumping when swallowed. They could change the route of administration. For example the abuser could crush a tablet and then try and inject or snort the contents of the crushed tablet. Thus, abuse deterrent formulations are investigated to identify the failure modes. This knowledge will lead to second generation formulations that are even more difficult to abuse than those currently on the market.

**Engagement Program Co-Founded – Chao Center now Purdue GMP Center:**

The Chao Center is a self-supporting manufacturing facility located in the Purdue Research Park. A major donor, Dr. Allan Chao, established the Center with a very substantial gift of $5.0 million. The Chao Center is involved in contract research and manufactures the anti-tuberculosis drug Seromycin for Lilly.

**Publications (Books):**

Byrn, S.R., "Solid State Chemistry of Drugs," Academic Press, New York, New York, l982.

Knevel, A.M., DiGangi, F.E., and Byrn, S.R., "Quantitative Pharmaceutical Chemistry," 7th Edition, Waveland Press, Inc., Prospect Heights, Illinois, l983.

Byrn, S.R., Stowell, J.G., and Pfeiffer, R.R., Solid State Chemistry of Drugs," 2nd Edition, SSCI Press, West Lafayette, IN, 1999

Byrn, S.R., Zografi, G., Chen, Xiaoming (Sean), "Solid State Properties of Pharmaceutical Materials," John Wiley and Co., Hoboken, NJ, 2017

**Publications (Book Co-Edited)**

Templeton, Allen; Byrn, Stephen R.; Haskell, Roy J.; Prisinzano, Thomas E., "Discovering and Developing Molecules with Optimum Drug-Like Properties", AAPS Press, Springer, NY, NY 2016

**Publications:**

1. Weingarten, H., Miles, M.G., Byrn, S.R., and Hobbs, C.F., *J. Am. Chem. Soc.*, l967, **89**, 5874, "Amination of $\beta$-Dicarbonyl Compounds with Tetrakis (dimethylamino) Titanium."

2. Curtin, D.Y. and Byrn, S.R., *J. Am. Chem. Soc.*, 1969, **91**, 1865, "Stereoisomrism at the Oxygen:Carbon Single Bond Due to Hydrogen Bonding. Structures of the Yellow and White Crystalline Forms of Dimethyl 3,6- Dichloro-2,5-Dihydroxy-terephthalate."

3. Curtin, D.Y. and Byrn, S.R., *J. Am. Chem. Soc.*, 1969, **91**, 6102, "Structures in Solution of the Yellow and White Forms of Dimethyl 3,6-Dichloro-2,5-Dihydroxyterephthalate."

4. Curtin, D.Y., Byrn, S.R., and Pendergrass, D.B., Jr., *J. Org. Chem.*, 1969, **34**, 3345, "Thermal Rearrangement of Arylazotribenzoyl-methanes in the Solid State. Examination with Differential Thermal Analysis."

5. Byrn, S.R., Maverick, E., Muscio, O.J., Trueblood, K.N., and Jacobs, T.L., *J. Am. Chem. Soc.*, 1971, **93**, 6680, "The Structure of Two Head to Head Allene Dimers."

6. Byrn, S.R., Curtin, D.Y., and Paul, I.C., *J. Am. Chem. Soc.*, 1972, **94**, 890, "The X-Ray Crystal Structure of the Yellow and White Forms of Dimethyl 3,6-Dichloro-2,5-Dihydroxyterephthalate and a Study of the Conversion of the Yellow Form to the White Form in the Solid State."

7. Wang, A.H.J., Misavage, R.J., Byrn, S.R., and Paul, I.C., *J. Am. Chem. Soc.*, 1972, **94**, 7100, "The Crystal and Molecular Structure of 1-Azabicyclo (3.3.3) Undecane Hydrochloride. Correlation of Molecular Dimensions with Spectroscopic Properties."

8. Byrn, S.R., *Biochemistry*, 1974, **13**, 5186, "The Cation-Binding Properties of Gramicidin."

9. Byrn, S.R., *Indiana Pharmacist*, 1974, **79**, "Caution Advised in Handling Neutral Red Dye."

10. Byrn, Stephen R., *Amer. Jour. Pharm. Ed.*, 1975, **40**, 295, "Combined BS:MS Programs: Alternatives for Pharmacy Students."

11. Byrn, S.R., *J. Pharm. Sci.*, 1976, **65**, 1-22, "Mechanisms of Solid-State Reactions of Drugs."

12. Byrn, S.R. and Lin, C.T., *J. Am. Chem. Soc.*, 1976, **98**, 4004, "The Effect of Crystal Packing and Defects on the Desolvation of Hydrate Crystals of Caffeine and L(-)-1,4-cyclohexadiene-1-alanine."

13. Byrn, S.R., Graber, C.W., and Midland, S.L., *J. Org. Chem.*, 1976, **41**, 2283, "Comparison of the Solid State and Solution Conformation of Methapyriline, Tripelennamine, Diphenhydramine, Histamine and Choline. The IR-X-Ray Method for Determination of Solution Conformation."

14. Byrn, S.R. and Siew, P.Y., *J. Chem. Soc.*, 1977, Perkin II, 144, "The Structure and Conformation of *β*-Thiodan in the Solid State and in Solution. Application of the IR-X-Ray Method."

15. Weintraub, H.J.R., Tsai, M.D., Byrn, S.R., Chang, C.-j., and Floss, H.G., *Int. J. Quantum Chem., Quantum Biology Symp.*, 1976, **3**, 99, "Conformational Analysis of Some Pyridoxal Amino Acid Schiff Bases."

16. Stamos, I.K., Howie, G.A., Manni, P.E., Haws, W.J., Byrn, S.R., and Cassady, J.M., *J. Org. Chem.*, 1977, **42**, 1703, "Synthesis and Structures of Dilactones Related to Anemonin."

17. Otten, J.G., Yeh, C.S., Byrn, S.R., and Morrison, H.A., *J. Amer. Chem. Soc.*, 1977, **99**, 6353, "Solution Phase Photodimerization of Tetramethyl Uracil. Further Studies of Ground-State Aggregates."

18. Byrn, S.R. and Dolch, G.D., *J. Pharm. Sci.*, 1978, **67**, 688, "Analysis of the Binding of Daunomycin and Doxorubicin to DNA Using Computerized Curve Fitting Procedures."

19. Lin, C.T., Siew, P.Y., and Byrn, S.R., *J. Chem. Soc.*, 1978, Perkin II, 957, "Solid State Dehydrochlorination and Decarboxlation Reactions I. Reactions of *p*-Aminosalicylic Acid Hydrochloride and *p*-Aminosalicylic Acid and the Crystal Structure of *p*-Aminosalicylic Acid."

20. Lin, C.T., Siew, P.Y., and Byrn, S.R., *J. Chem. Soc.*, 1978, Perkin II, 963, "Solid State Dehydrochlorination and Decarboxylation Reactions II. Reactions of Three Crystal Habits of *p*-Aminosalicylic Acid Hydrochloride and the Crystal Structure of *p*-Aminosalicylic Acid Hydrochloride."

21. Tsai, M.D., Weintraub, H.J.R., Byrn, S.R., Chang, C.-j., Floss, H.G., *Biochemistry*, 1978, **17**, 3183, "Conformational-Reactivity Relationships for Pyridoxal Schiff's Bases of Amino Acids."

22. Tsai, M.D., Byrn, S.R., Chang, C.-j., Floss, H.G., and Weintraub, H.J.R., *Biochemistry*, 1978, **17**, 3177, "Conformational Analysis of Pyridoxal Schiff's Bases. NMR Studies of the Conformation about the $C_4$-$C_{4'}$, C-C, and N-C Bonds of the Pyridoxal Schiff's Bases of Amino Acids."

23. Cassady, J.M., Byrn, S.R., Stamos, I.K., Evans, S.M., and McKenzie, A., *J. Med. Chem.*, 1978, **21**, 815, "Potential Antitumor Agents. Synthesis, Reactivity and Cytotoxicity of Alpha-Methylene Carbonyl Compounds."

24. Lin, C.T. and Byrn, S.R., *Tetrahedron Letters*, 1978, **1975**, "Solvolysis of Hydrazobenzene in Methyl Iodide."

25. Lin, C.T. and Byrn, S.R., *Mol. Cryst. and Liq. Cryst.*, 1979, **50**, 99, "Desolvations of Solvated Organic Crystals."

26. Lin, C.T. and Byrn, S.R., *Tet. Lett.*, 1979, **4623**, "Solid Gas Reaction of Hydrazobenzene with Methyl Iodide."

27. Migliaccio, G.P. and Byrn, S.R., *J. Pharm. Sci.*, 1981, **70**, 284, "Comparisons of the Rotamer Populations of Nialamide, Chloroquine and Azaperone in the Solid State and in Solution."

28. Siew, P.Y. and Byrn, S.R., *J. Pharm. Sci.*, 1981, **70**, 280, "The Crystal Structure and Solid State Behavior of Aspirin Anhydride."

29. Pyne, S.G., Hensel, M.J., Byrn, S.R., McKenzie, A.T., and Fuchs, P.L., *J. Amer. Chem. Soc.*, 1980, **102**, 5960, "Cytochalasin Support Studies, Chiral and Stereochemical Control via an Intramolecular Diels-Alder Reaction of a (Z-)-Diene."

30. Migliaccio, G.P., Shieh, T.L., Byrn, S.R., Hathaway, B.A., and Nichols, D.E., *J. Med. Chem.*, 1981, **70**, 284, "Comparison of Solution Conformational Preferences for the Hallucinogens Bufotenin and Psilocin using 360 MHz Proton NMR Spectroscopy."

31. Chang, C.-j., Gomes, J.D., and Byrn, S.R., *J. Amer. Chem. Soc.*, 1981, **103**, 2892, "Chemical Modification of Deoxyribonucleic Acids: A Direct Study by NMR Spectroscopy."

32. Clay, G.G., Byrn, S.R., and Heinstein, P.H., *J. Pharm. Sci.*, 1982, **71**, 467, "The Interaction of Gramacitin with Nucleic Acids and Pyruvate Decarboxylase."

33. Perrier, P. and Byrn, S.R., *J. Org. Chem.*, 1982, **47**, 4671, "The Influence of Crystal Packing on the Desolvation of Purine and Pyrimidine Hydrates."

34. Perrier, P. and Byrn, S.R., *J. Org. Chem.*, 1982, **47**, 4677, "Dehydration of Glucuronamide Hydrate. Confirmation of the Predicted Influence of Crystal Packing on Dehydration Reactions."

35. Lin, C.T., Perrier, P., Clay, G.G., Sutton, P.A., and Byrn, S.R., *J. Org. Chem.*, 1982, **47**, 2978, "Solid State Photooxidation of Coritisol-21-tert-butylacetate to Cortisone-21-tert-butylacetate."

36. Shieh, T.L. and Byrn, S.R., *J. Med. Chem.*, 1982, **25**, 403, "The Solution Conformation of the Thermolysin Inhibitors Carbobenzoxy-*L*-phenylalanine and $\beta$-Phenylpropionyl-*L*-phenylalanine and Comparison of the Solution Conformation to the Enzyme Bound Conformation."

37. Clay, R.J., Knevel, A.M., and Byrn, S.R., *J. Pharm. Sci.*, 1982, **71**, 1289, "The Desolvation and Oxidation of Crystals of Dialuric Acid Monohydrate."

38. Shieh, T.L., Lin, C.T., McKenzie, A.T., and Byrn, S.R., *J. Org. Chem.*, 1983, **26**, 3103, "Relationship Between the Solid State and Solution Conformations of $\beta$-benzylaminocrotonate."

39. Donaldson, R.E., Saddler, J.C., Byrn, S.R., McKenzie, A.T., and Fuchs, P.L., *J. Org. Chem.*, 1983, **48**, 2167, "A Triply Convergent Total Synthesis of *L*-(-)-Prostaglandin $E_2$."

40. Chang, C.J., DaSilva Gomes, J., and Byrn, S.R., *J. Org. Chem.*, 1983, **48**, 5151, "Chemical Modification of Deoxyribonucleic Acids: A Direct Study by Carbon-13 Nuclear Magnetic Resonance Spectroscopy."

41. Stewart, B.S., Midland, S.L. and Byrn, S.R., *J. Pharm. Sci.*, 1984, **73**, 1322-1323, "Degradation of Crystalline Ergocalciferol."

42. Ebrahim El-Zayat, A.A., Ferringni, N.R., McCloud, T.G., McKenzie, A.T., Byrn, S.R., Cassady, J.M., Chang, C.-j., and McLaughlin, J.L., *Tetrahedron Letters*, 1985, **26**, 955, "Goniothalenol: A Novel, Bioactive, Tetrahydrofurano-2-pyrone from *Goniothalamus giganteus* (Annonaceae)."

43. Mossa, J.S., Cassady, J.M., Antoun, M.D., Byrn, S.R., McKenzie, A.T., Kozlowski, J.F. and Main, P., *J. Org. Chem.*, 1985, **50**, 916-918, "Saudin, a Hypoglycemic Diterpenoid with a Novel 6,7-Secolabdane Carbon Skeleton, from *Cluytia richardiana*."

44. Byrn, S.R., Gray, G., Frye, J., and Pfeiffer, R.R., *J. Pharm. Sci.*, 1985, **73**, 565-568, "Analysis of Solid-State Carbon-13 NMR Spectra of Polymorphs (Benoxaprofen and Nabilone) and Pseudopolymorphs (Cefaolin)."

45. Byrn, S.R., Chapter 29. Solid State Organic Chemistry and Drug Stability, Annual Reports in Medicinal Chemistry, 1986, 287-294.

46. Byrn, S.R., McKenzie, A.T., Hassan, M.M.A., and Al-Badr, A.A., *J. Pharm. Sci.*, 1986, **75**, 596-600, "Conformation of Glyburide in the Solid State and in Solution."

47. Byrn, S.R. and Kessler, D.W., *Tetrahedron*, 1987, **43**, 1335-1343, "The Solid State Reactivity of the Crystal Forms of Hydrocortisone Esters."

48. Sutton, P.A. and Byrn, S.R., *J. Pharm. Sci.*, 1987, **76**, 253-258, "The Crystal Structure of Two Crystal Forms of 9$\alpha$-Fluorocortisol Acetate. Variation of the Conformation of the A Ring of Steroids due to Crystal Packing."

49. Byrn, S.R., Perrier, P., Lin, C.T., Martinez, H., and Pfeiffer, R.R., *Pharmaceutical Research*, 1987, **4**, 137-141, "The Solid State Decarboxylation of the Diammonium Salt of Moxalactam."

50. Ho, D.K., McKenzie, A.T., Byrn, S.R., and Cassady, J.M, *J. Org. Chem.*, 1987, **52**, 342-347, "$O^5$-Methyl-(q)-2′*R*,3′*S*-Psorospermin."

51. Hedstrand, D.M., Byrn, S.R., McKenzie, A.T. and Fuchs, P.L., *J. Org. Chem.*, 1987, **52**, 592-598, "Use of an Axian $\beta$-Face Thiomethyl Control Element in Intramolecular Conjugate Additions. Synthesis of a Tricyclic Bruceantin Precursor."

52. Byrn, S.R., Sutton, P.A., and Tobias, B., *J. Am. Chem. Soc.*, 1988, **110**, 1609-1614, "The Crystal Structure, Solid State NMR Spectra, and Oxygen Reactivity of Five Crystal Forms of Prednisolone tert-butylacetate."

53. Riggs, Robert M., McKenzie, Ann T., Byrn, Stephen R., Nichols, David E., Foreman, Mark M., and Truex, Lewis L., *J. Med. Chem.*, 1987, **30**, 1914-18, "Effect of $\beta$-Alkyl Substitution on D-1 Dopamine Agonist Activity: Absolute Configuration of $\beta$-Methyldopamine."

54. Habib, A.M., Ho, David K., Masuda, S., McCloud, T., Reddy, K.S., Aboushoer, M., McKenzie, A., Byrn, S. R., Chang, Ching Jer,and Cassady, John M. *J. Org. Chem.*, 1987, **52**, 412-18, "Structure and Stereochemistry of Psorospermin and Related Cytotoxic Dihydrofuranoxanthones from *Psorospermum febrifugum*."

55. Mossa, Jaber S., Cassady, John M., Kozlowski, John F., Zennie, Thomas M., Antoun, Mikhail D., Pellechia, Marianne G., McKenzie, Ann T., and Byrn, Stephen R., *Tetrahedron Lett.*, 1988, **29**, 3627-30, "Novel 6,7-seco-6,11-cyclolabdane Diterpenes from *Cluytia richardiana*."

56. Lassalle, I., Hoyos, P.H., Byrn, S.R., Weith, H.L., *Nucleosides and Nucleotides,* 1989, **6**, 1071, "Sequence Preference of Acridine Interaction with Single and Double Stranded Octadeoxyribonucleotides."

57. Cushman, M., Patrick, D., Toma, P., Byrn, S.R., *Tetrahedron Letters,* 1989, **30**, 7161-7164, "A Novel ring System from Intramolecular Oxidative Cyclization of 8-(4-Pentenyl)dihydroberberine."

58. Martinez, H., Byrn, S. R., Pfeiffer, R.R., *Pharm. Res.,* 1990, **7**, 147-153, "Solid State Chemistry and Crystal Structure of Cefaclor Dihydrate."

59. Shieh, T.L., Hoyos, P., Kolodziej, E., Stowell, J.G., Baird, W.M., Byrn, S. R., *J. Med. Chem.*, 1990, **33**, 1225-1230, "Properties of the Nucleic Acid Photoaffinity Labeling Agent, 3-Azido-Amsacrine."

60. Byrn, S.R., Ray, K., Stowell, J.G., Toma, P., *Acta Cryst., Sect. C,* 1990, **C46**, 1573-1576, "Crystal Structure of Acridinyl Ethanol."

61. Alkofahi, A., Ma, W.W., McKenzie, A.T., Byrn, S.R., McLaughlin, J.L., *J. Natural Products*, 1989, **52**, 1371-1373.

62. Ma, W.W., Anderson, J.E., McKenzie, A.T., Byrn, S.R., McLaughlin, J.L., and Hudson, M.S., *J. Nat. Prod.,* 1990, **63**, 1009-1014, "Tubulosine: An Antitumor Constituent of *Pogonopus speciosus*."

63. Pidgeon, C., Weith, H.L., Darbishire-Weith, D., Cushman, M., Byrn, S.R., Chen, J.-K., Stowell, J.G., Ray, K., and Carlson, D., *Anals. New York Acad. Sci.,* 1991, **616**, 593-596, "Synthesis and Liposome Encapsulation of Antisense Oligonucleotides-Intercalator Conjugates."

64. Byrn, S.R., Tobias, B., Kessler, D., Frye, J., Sutton, P. Saindon, P., and Kozlowski, J., *Trans. Amer. Cryst. Assoc.,* 1989, **24**, 41-54, "Relationship Between Solid State NMR and Crystal Structures of Polymorphs and Solvates of Drugs."

65. Byrn, S.R., Carlson, D.V., Chen, J.K., Cushman, M.S., Goldman, M.E., Ma, W.P., Pidgeon, C.L., Ray, K.A., Stowell, J.G., and Weith, H.L., *Adv. Drug. Delivery Rev.,* **6**, 1991, 287-308, "Drug-Oligonucleotide Conjugates."

66. Stowell, J.G., Toma, P.H., and Byrn, S.R., *Acta Cryst.,* **C47**, 1991, 1635-1637, "9,10-Dihydro-9-methylacridine."

67. Stowell, J.G., Toma, P.H., and Byrn, S.R., *Acta Cryst.,* **C47**, 1991, 1637-1640, "9-Phenylacridine and 9-Phenylacridine Hydrochloride."

68. Stowell, J.G., Toma, P.H., and Byrn, S.R., *Biorg. and Med. Chem. Letters,* **2**, 1992, 185-190, "The Structure of MK-571 (Form I) at 170K and Conformational Analysis by Molecular Modeling."

69. Saindon, P.J., Cauchon, N.S., Sutton, P.A., Chang, C.J., Peck, G.E., and Byrn, S.R., *Pharm. Res.,* **10**, 1993, 197-203, "Solid-State NMR Spectra of Pharmaceutical Dosage Forms."

70. Dalla Riva Toma, J.M., Toma, P.H., Fanwick, P.E., Bergstrom, D.E., Byrn, S.R., *J. Cryst. and Spect. Res.*, **23**, 1993, 41-47. Photochemical Synthesis and Crystal Structure of two Potentially Useful Metal Carbonyl Complexes: Pentacarbonyl ($\eta^2$-*cis*-cyclooctene)-tungsten(0) and tetracarbonylbis ($\eta^2$-*cis*-cyclooctene)-tungsten(0).

71. Toma, P.H., Nguyen, D.N., Byrn, S.R., *Acta Cryst., C**49**, 1993, 914-916.* 9-Chloro-2-ethoxy-6-nitroacridine.

72. Stephenson, G.A., Stowell, J.G., Toma, P.A., Dorman, D.E., Greene, J.R., and Byrn, S.R., *J. Am. Chem. Soc.,* **116**, 5766 (1994). Solid-state analysis of Polymorphs, Isomorphic, and Solvated Forms of Dirithromycin.

73. Ma, Wu Po, Hamilton, S.E., Stowell, J.G., Byrn, S.R., and Davisson, V.J., *Biorg. & Med. Chemistry,* **2**, 169-179 (1994). Sequence Specific Cleavage of Messenger RNA by a Modified Ribonuclease H.

74. Byrn, S.R., Pfeiffer, R.R., Stephenson, G., Grant, D.J.W., and Gleason, W.B., *Chemistry of Materials*, **6**, 1148 (1994). Solid-State Pharmaceutical Chemistry.

75. Toma, P.H., Kelley, M.P., Borchardt, T.B., Byrn, S.R., and Kahr, B., *Chemistry of Materials,* 6, 1317 (1994). Chromoisomers and Polymorphs of 9-Phenylacridinium Hydrogen Sulfate.

76. Huang, K.-S., Britton, D., Etter, M.C., and Byrn, S.R., *J. Materials Chemistry*, 1995, **5**, 379-383. Polymorphic Characterization and Structural Comparisons of the NLO Active and Inactive Forms of Two Polymorphs of 1,3-Bis(m-nitrophenyl)urea.

77. Byrn, S.R., Pfeiffer, R.R., Ganey, M., Hoiberg, C., and Poochikian, G., *Pharm Res*. 12, 945-954 (1995). Pharmaceutical Solids: A Strategic approach to Regulatory Considerations.

78. Saleki-Gerhardt, A., Stowell, J.G., Byrn, S.R., and Zografi, G., *J. Pharm. Sci.* 84, 318-323 (1995). Hydration and Dehydration of Crystalline and Amorphous Forms of Raffinose.

79. Byrn, S. R. and J. G. Stowell *J. Drug Targeting* 3(4): 239-41 (1995). "Drug targeting using conjugates: the importance of pharmaceutical chemistry.".

80. Akers, M. J., N. Milton, et al. *Pharm. Res* 12(10): 1457-61 (1995). "Glycine crystallization during freezing: the effects of salt form, pH, and ionic strength."

81. Huang, K. S., D. Britton, Etter, M.C., and Byrn, S.R.;*J. Mater. Chem* 5(3): 379-83 (1995). "Polymorphic characterization and structural comparisons of the non-linear optically active and inactive forms of two polymorphs of 1,3-bis(m-nitrophenyl)urea.".

82. Huang, K. S., D. Britton, Etter, M.C., and Byrn, S.R.; *J. Mater. Chem* 6(2): 123-9 (1996). "Synthesis, polymorphic characterization and structural comparisons of the non-linear optically active and inactive forms of polymorphs of 3-(nitroanilino)cycloalk-2-en-1-ones.".

83. Morales, L., Stowell, J.G, and Byrn, S.R.; *Rev. Boliv. Quim* 12(1): 59-67(1995). "Alkyl substituted acridine synthesis. I. Organometallic synthesis.".

84. Stephenson, G. A., Borchardt, T. B., Bunnell, C., Snorek, S., Bowyer, J., Yu, L., and Byrn, S, *J. Pharm. Sci* 84(11): 1385-6. (1995). "Conformational and Color Polymorphism of 5-Methyl-2-[(2- nitrophenyl)amino]-3-thiophenecarbonitrile."

85. Wahle, M.C., Stowell, J.G., and Byrn, S.R., *Acta Crystallogr., Sect. C, Cryst. Struct. Commun.,* c52, 325-8 (1996). "Sodium 3α, 7α, 12α-trihydroxy-5β-cholan-24-oate ethanolate (sodium cholate ethanolate)."

87. Wahle, M.C., and Byrn, S.R., *Acta Crystallogr., Sect. C, Cryst. Struct. Commun.,* C52, 2495-2499 (1996). "Sodium Cholate Methanolate and Sodium Cholate 2-Propanolate."

88. Wahle, M.C. and Byrn, S.R., *Acta Crystallogr., Sect. C, Cryst. Struct. Commun.,* C52, 2500-2502 (1996). "3α, 7α, 12α-Trihydroxy-5β-cholan-24-oic Acid Methyl Ester Ethanolate (Methyl Cholate Ethanolate)."

89. Stephenson, G.A., Wozniak, T.J., Stowell, J.G., and Byrn, S.R., *J. Mol. Struct.,* 380, 93-100 (1996). "Nizatidine, N-[2-[[[2[(dimethylamino)methyl]-4-thiazoyl]methyl]thio]ethyl]-N'-methyl-2-nitro-1,1-ethenediamine."

90. Stephenson, Gregory A.; Pfeiffer, Ralph R.; Byrn, Stephen R., *Int. J. Pharm*., 146(1), 93-99 (1997). Solid-state investigation of the tautomerism of acetohexamide.

91. Wahle, Mark C. and Byrn, Stephen R., *Acta Crystallogr., Sect. C: Cryst. Struct. Commun.,* C53(3), 334-339 (1997). Hydrated structures of N-methylated cholamide derivatives.

92. Kim, Chinpal; MacKellar, Warren C.; Cho, NaMi; Byrn, Stephen R. ; Morre, D. James, *Biochim. Biophys. Acta*, 1324(2), 171-181 (1997). Impermeant antitumor sulfonylurea conjugates that inhibit plasma membrane NADH oxidase and growth of HeLa cells in culture. Identification of binding proteins from sera of cancer patients.

93. Wahle, Mark C.; Fanwick, Phillip E.; Byrn, Stephen R., *Acta Crystallogr., Sect. C: Cryst. Struct. Commun.,* C53(4), 480-482 (1997). Cholamide dihydrate.

94. Shalaev, Evgenyi Yu.; Byrn, Stephen R.; Zografi, George, *Int. J. Chem. Kinet.,* 29(5), 339-348 (1997). Single-phase and heterophase solid-state chemical kinetics of thermally induced methyl transfer in tetraglycine methyl ester.

95. Huang, Kin-Shan; Britton, Doyle; Etter, Margaret C.; Byrn, Stephen R., *J. Mater. Chem.,* 7(5), 713-720 (1997). A novel class of phenol-pyridine co-crystals for second harmonic generation.

96. Stahly, G. Patrick; McKenzie, Ann T.; Andres, Mark C.; Russell, Catherine A.; Byrn, Stephen R.; Johnson, Pete , *J. Pharm. Sci.,* 86(8), 970-971 (1997). Determination of the Optical Purity of Ibuprofen Using X-ray Powder Diffraction.

97. Shalaev, Evgenyi Yu.; Shalaeva, Marina; Byrn, Stephen R.; Zografi, George, *Int. J. Pharm.,* 152(1), 75-88 (1997). Effects of processing on the solid-state methyl transfer of tetraglycine methyl ester.

98. Stephenson, Gregory A.; Stowell, Joseph G.; Toma, Pascal H.; Pfeiffer, Ralph R.; Byrn, Stephen R., *J. Pharm. Sci.,* 86(11), 1239-1244 (1997). Solid-State Investigations of Erythromycin A Dihydrate Structure, NMR Spectroscopy, and Hygroscopicity.

99. Xu, Wei; Wahle, Mark C.; Stowell, Joseph G.; Byrn, Stephen R., *Acta Crystallogr., Sect. C: Cryst. Struct. Commun.,* C53(12), 1917-1919 (1997). Spirapril hydrochloride hydrate.

100. Joshi, Vidya; Stowell, Joseph G.; Byrn, Stephen R. Mol. Cryst. Liq. Cryst. Sci. Technol., Sect. A, 313, 265-270 1998. Solid-state stability of indomethacin solvates.

101. Borchardt, Thomas B.; Stowell, Joseph G.; Byrn, Stephen R. Mol. Cryst. Liq. Cryst. Sci. Technol., Sect. A, 313, 271-276 (English) 1998. The crystallization of 5-methyl-2-[(2-nitrophenyl)amino]-3-thiophenecarbonitrile in the presence of structurally similar compounds.

102. Morris, K.R., Nail, S.L., Peck, G.E., Byrn, S.R., Griesser, U.J., Stowell, J.G., Hwang, S-J, Park, K, "Advances in pharmaceutical materials and processing", Pharmaceutical Science and Technology Today, Volume 1, No. 6, September 1998.

103. Smith, Jay; MacNamara, Ernesto; Raftery, Daniel; Borchardt, Thomas; Byrn, Stephen J. Am. Chem. Soc., 120(45), 11710-11713 (English) 1998. Application of Two-Dimensional 13C Solid-State NMR to the Study of Conformational Polymorphism.

104. Chongprasert, Suchart; Griesser, Ulrich J.; Bottorff, Arthur T.; Williams, N. Adeyinka; Byrn, Stephen R., Nail, Steven L . J. Pharm. Sci., 87(9), 1155-1160 Effects of Freeze-Dry Processing Conditions on the Crystallization of Pentamidine Isethionate.

105. Yu, Lian; Stephenson, Gregory A.; Mitchell, Christine A.; Bunnell, Charles A.; Snorek, Sharon V.; Bowyer, J. Joe; Borchardt, Thomas B.; Stowell, Joseph G.; Byrn, Stephen R. J. Am. Chem. Soc., 122(4), 585-591, 2000. Thermochemistry and Conformational Polymorphism of a Hexamorphic Crystal System.

106. Guo, Yushen; Byrn, Stephen R., Zografi, George; Pharm. Res., 17(8), 930-935 2000. Effects of lyophilization on the physical characteristics and chemical stability of amorphous quinapril hydrochloride.

107. Guo, Yushen; Byrn, Stephen R., Zografi, George; J. Pharm. Sci., 89, 128-143, 2000. Physical characteristics and chemical degradation of amorphous quinapril hydrochloride.

108. Morris, Kenneth R.; Stowell, Joseph G.; Byrn, Stephen R.; Placette, Allen W.; Davis, Tiffani D.; Peck, Garnet E.; Drug Dev. Ind. Pharm., 26(9), 985-988, 2000. Accelerated fluid bed drying using NIR monitoring and phenomenological modeling.

109. Zografi, Z., Byrn, S.R., Symposium on the Properties of Water in Foods], Helsinki, Finland, May 30-June 4, 1998, Meeting Date 1998, 397-410. Editor(s): Roos, Yrjo H.; Leslie, R. B.; Lillford, Peter J. Technomic Publishing Co., Inc.: Lancaster, Pa. (English) 1999. The effects of residual water on solid-state stability of drugs and drug products.

110. He, Xiaorong; Griesser, Ulrich J.; Stowell, Joseph G.; Borchardt, Thomas B.; Byrn, S.R. ; J. Pharm. Sci., 90, 371, 2001. Conformational color polymorphism and control of crystallization of 5-methyl-2-[(4-methyl-2-nitrophenyl)amino]-3-thiophenecarbonitrile.

111. He, Xiaorong; Stowell, Joseph G.; Morris, Kenneth R.; Pfeiffer, Ralph R.; Li, Hui; Stahly, G. Patrick; Byrn, Stephen R.; Stabilization of a Metastable Polymorph of 4-Methyl-2-nitroacetanilide by Isomorphic Additives. Crystal Growth and Design, 1, 305-312, 2001.

112. Byrn, S. R.; Xu, W.; Newman, A. W.; Chemical reactivity in solid-state pharmaceuticals: formulation implications. Advanced Drug Delivery Reviews, 48(1), 115-136, 2001.

113. Pagola, S.; Stephens, P. W.; He, X.; Byrn, S. R.; Crystal structure solution of the dark red, light red and orange polymorphs of 5-methyl-2-[(2-nitro-4-methylphenyl)amino]-3-thiophenecarbonitrile by high resolution X-ray powder diffraction and simulated annealing techniques. Materials Science Forum, 378-381(Pt. 2, EPDIC 7, Part 2), 789-794 (English) 2001.

114. Reutzel-Edens, Susan M.; Bush, Julie K.; Magee, Paula A.; Stephenson, Greg A.; Byrn, Stephen R.; Anhydrates and Hydrates of Olanzapine: Crystallization, Solid-State Characterization, and Structural Relationships. Growth & Design, 3(6), 897-907, 2003

115. Griesser, Ulrich J.; Morris, Kenneth R.; Byrn, Stephen R.; Stowell, Joseph G. X-ray Diffraction and Solid-State NMR Investigation of the "Single-Crystal to Single-Crystal Dehydration of Thiamine Hydrochloride." Crystal Growth & Design, 3(6), 997-1004, 2003

116. Tishmack, Patrick A.; Bugay, David E., Byrn, Stephen R., "Solid-state nuclear magnetic resonance spectroscopy-pharmaceutical applications." Journal of Pharmaceutical Sciences, 92(3), 441-474 (English) 2003

117. Chen, Xiaoming; Morris, Kenneth R.; Griesser, Ulrich J.; Byrn, Stephen R. ; Stowell, Joseph G. "Reactivity Differences of Indomethacin Solid Forms with Ammonia Gas." Journal of the American Chemical Society, 124(50), 15012-15019, 2002.

118. Newman, Ann W.; Byrn, Stephen R., "Solid-state analysis of the active pharmaceutical ingredient in drug products." Drug Discovery Today, 8(19), 898 -905.

119. Davis, Tiffani D.; Morris, Kenneth R.; Huang, Huapeng; Peck, Garnet E.; Stowell, Joseph G.; Eisenhauer, Bradley J.; Hilden , Jon L.; Gibson, David; Byrn, Stephen R, "In situ Monitoring of Wet Granulation Using Online X-Ray Powder Diffraction," Pharmaceutical Research, 20(11), 1851-1857, 2003.

120. Davis, Tiffani D.; Peck, Garnet E.; Stowell, Joseph G.; Morris, Kenneth R.; Byrn, Stephen R., "Modeling and Monitoring of Polymorphic Transformations During the Drying Phase of Wet Granulation." Pharmaceutical Research, 21 (5), 860-866, 2004.

121. Stephen R. Byrn, Simon Bates, and Igor Ivanisevic. Regulatory Aspects of X-ray Powder Diffraction, Part I. American Pharmaceutical Review, 8(3), 55-59 May/Jun 2005.

122. Stephen R. Byrn, Simon Bates, and Igor Ivanisevic. Regulatory Aspects of X-ray Powder Diffraction, Part II. American Pharmaceutical Review, 8(4), 137-141 Jul/Aug 2005.

123. Stephen Byrn, Kenneth Morris, Shawn Comella, Reducing Time to Market with A Science-Based Product Management Strategy, Pharmaceutical Technology, Aug. 1, 2005.

124. Terakita, Akira; Byrn, Stephen R., Structure and physical stability of hydrates and thermotropic mesophase of calcium benzoate. Journal of Pharmaceutical Sciences, 95(5), 1162-1172, 2006.

125. McBride, Jennifer M.; Smith, Daniel T.; Byrn, Stephen R.; Borgens, Richard B.; Shi, Riyi Dose responses of three 4-aminopyridine derivatives on axonal conduction in spinal cord trauma. European Journal of Pharmaceutical Sciences, 27(2-3), 237-242, 2006.

126. Qiu, Zhihui; Stowell, Joseph G.; Cao, Wenjin; Morris, Kenneth R.; Byrn, Stephen R.; Carvajal, M. Teresa. Effect of milling and compression on the solid-state Maillard reaction. . Journal of Pharmaceutical Sciences, 94(11), 2568-2580, 2005.

127. Qiu, Zhihui; Stowell, Joseph G.; Morris, Kenneth R.; Byrn, Stephen R.; Pinal, Rodolfo Kinetic study of the Maillard reaction between metoclopramide hydrochloride and lactose. International Journal of Pharmaceutics, 303(1-2), 20-30, 2005.

128. Chen, Xiaoming; Griesser, Ulrich J.; Te, Ruth L.; Pfeiffer, Ralph R.; Morris, Kenneth R.; Stowell, Joseph G.; Byrn, Stephen R., Analysis of the acid-base reaction between solid indomethacin and sodium bicarbonate using infrared spectroscopy, X-ray powder diffraction, and solid-state nuclear magnetic resonance spectroscopy. Journal of Pharmaceutical and Biomedical Analysis, 38(4), 670-677, 2005.

129. Smith, Daniel T.; Shi, Riyi; Borgens, Richard B.; McBride, Jennifer M.; Jackson, Kevin; Byrn, Stephen R. Development of novel 4-aminopyridine derivatives as potential treatments for neurological injury and disease. European Journal of Medicinal Chemistry, 40(9), 908-917, 2005.

130. Byrn, Stephen R.; Pfeiffer, Ralph R.; Stowell, Joseph G. Polymorphs, regulations, crystallization, and solid-state chemistry. American Pharmaceutical Review, 5(3), 92, 94, 96-99, 2002.

131. Hu, Yuerong; Wikstrom, Hakan; Byrn, Stephen R.; Taylor, Lynne S. Analysis of the effect of Particle size on Polymorphic Quantitation by Raman spectroscopy. Applied Spectroscopy, 60(9), 977-984, 2006.

132. Atassi, Faraj; and Byrn, Stephen R. General Trends in the Desolvation Behavior of Calcium Salts. Pharmaceutical Research, 23(10), 2405-2412, 2006.

133. Li, Hui; Stowell, Joseph G.; Borchardt, Thomas B.; Byrn, Stephen R. Synthesis, Conformational Polymorphism, and Construction of a G-T Diagram of 2-[(2-Nitrophenyl)amino]-3-thiophenecarbonitrile. Crystal Growth & Design, 6(11), 2469-2474, 2006.

134. Mao, Chen; Chamarthy, Sai Prasanth; Byrn, Stephen R. ; Pinal, Rodolfo A Calorimetric Method to Estimate Molecular Mobility of Amorphous Solids at Relatively Low Temperatures. Pharmaceutical Research, 23(10), 2269-2276, 2006.

135. Crooks, Peter A.; Kottayil, Santosh G.; Al-Ghananeem, Abeer M.; Byrn, Stephen R.; Butterfield, D. Allan Opiate receptor binding properties of morphine-, dihydromorphine-, and codeine 6-O-sulfate ester congeners. Bioorganic & Medicinal Chemistry Letters, 16(16), 4291-4295, 2006.

136. Henck, Jan-Olav; and Byrn, Stephen R., Designing a Molecular Delivery System in a Preclinical Timeframe, Drug Discovery Today, 12, 189-199 (2007)

137. Li, Hui; Stowell, Joseph G.; He, Xiaorong; Morris, Kenneth R.; Byrn, Stephen R., Investigations on solid-solid phase transformation of 5-methyl-2-[(4-methyl-2-nitrophenyl)amino]-3-thiophenecarbonitrile. Journal of Pharmaceutical Sciences 96(5), 1079-1089 (2007).

138. McBride, J. M.; Smith, D. T.; Byrn, S. R.; Borgens, R. B.; Shi, R. 4-Aminopyridine derivatives enhance impulse conduction in guinea-pig spinal cord following traumatic injury. Neuroscience, 148(1), 44-52 (2007).

139. Liang, Jessica K.; Byrn, Stephen. On-line Raman spectroscopy in pharmaceutical process development: application and future prospects. American Pharmaceutical Review 10(4), 45-51 (2007).

140. Hu, Yuerong; Wikstroem, Hakan; Byrn, Stephen R.; Taylor, Lynne S. Estimation of the transition temperature for an enantiotropic polymorphic system from the transformation kinetics monitored using Raman spectroscopy. Journal of Pharmaceutical and Biomedical Analysis, 45(4), 546-551 (2007).

141. Chongcharoen, Wanchai; Byrn, Stephen; Sutanthavibul, Narueporn; Solid state interconversion between anhydrous norfloxacin and its hydrates, Journal of pharmaceutical Sciences, 97 (1), 473-489 (2007).

142. Lee, Eun Hee; Boerrigter, Stephan X.; Rumondor, Alfred C.; Chamarthy, Sai P.; and Byrn, Stephen R., Formation and Solid-State Characterization of a Salt-Induced Metastable Polymorph of Flufenamic Acid, Crystal Growth and Design, 8 (1), 91-97 (2008).

143. Byrn, Stephen; Liang, Jessica; Bates, Simon; Newman, Ann; PAT – Process Understanding and Control of Active Pharmaceutical Ingredients; PAT – The Journal of Process Analytical Technology, 3 (6), 14-19 (2006).

144. Lee, EunHee; Byrn, Stephen; Carvajal, Teresa; Additive Induced Metastable Single Crystal of Mefenamic Acid; Pharmaceutical Research, 23 (10), 2375-2380 (2006).

145. Joshi, Vidya; Morris, Kenneth R.; Byrn, Stephen R.; Carvajal, M. Teresa, Evaluation of the Use of Ea (Activation Energy) as a Quantitative Indicator of Physical Stability of Indomethacin Solvates: Methanolate and Tertiary Butyl Alcohol Solvate, Crystal Growth & Design 9(8), 3359-3366. (2009).

146. Chen, Xiaoming; Stowell, Joseph G.; Morris, Kenneth R.; Byrn, Stephen R., Quantitative study of solid-state acid-base reactions between polymorphs of flufenamic acid and magnesium oxide using X-ray powder diffraction. Journal of Pharmaceutical and Biomedical Analysis (2010), 51(4), 866-874.

147. Lee, Eun Hee; Boerrigter, Stephan X. M.; Byrn, Stephen R., Epitaxy of a Structurally Related Compound on the (100) Faces of Flufenamic Acid Form I and III Single Crystals. Crystal Growth & Design (2010), 10(2), 518-527.

148. Lee, Eun Hee; Smith, Daniel T.; Fanwick, Phillip E.; Byrn, Stephen R., Characterization and Anisotropic Lattice Expansion/Contraction of Polymorphs of Tenofovir Disoproxil Fumarate. Crystal Growth & Design (2010), 10(5), 2314-2322.

149. Trasi, Niraj S.; Boerrigter, Stephan X. M.; Byrn, Stephen Robert, Investigation of the Milling-Induced Thermal Behavior of Crystalline and Amorphous Griseofulvin. Pharmaceutical Research (2010), 27(7), 1377-1389.

150. Atassi, Faraj; Mao, Chen; Masadeh, Ahmad S.; Byrn, Stephen R., Solid-state characterization of amorphous and mesomorphous calcium ketoprofen. Journal of Pharmaceutical Sciences (2010), 99(9), 3684-3697.

151. Byrn, Stephen R.; Zografi, George; Chen, Xiaoming. . Accelerating proof of concept for small molecule drugs using solid-state chemistry. From Journal of Pharmaceutical Sciences (2010), 99(9), 3839-3848.

152. Li, Hui; Wen, Hong; Stowell, Joseph G.; Morris, Kenneth R.; Byrn, Stephen R., Crystal quality and physical reactivity in the case of flufenamic acid (FFA). Journal of Pharmaceutical Sciences (2010), 99(9), 3839-3848.

153. Engers, David; Teng, Jing; Jimenez-Novoa, Jonathan; Gent, Philip; Hossack, Stuart; Campbell, Cheryl; Thomson, John; Ivanisevic, Igor; Templeton, Alison; Byrn, Stephen; et al., A solid-state approach to enable early development compounds: selection and animal bioavailability studies of an itraconazole amorphous solid dispersion. Journal of Pharmaceutical Sciences (2010), 99(9), 3901-3922.

155. Ripin, David H. Brown; Teager, David S.; Fortunak, Joseph; Basha, Shaik Mahaboob; Bivins, Nylea; Boddy, Christopher N.; Byrn, Stephen; Catlin, Kelly K.; Houghton, Stephen R.; Jagadeesh, S. Tirumala; et al., Process Improvements for the Manufacture of Tenofovir Disoproxil Fumarate at Commercial Scale. Organic Process Research & Development (2010), 14(5), 1194-1201.

156. Emeje, Martins; Olaleye, Olajide; Isimi, Christiana; Fortunak, Joseph; Byrn, Stephen; Kunle, Olobayo; Ofoefule, Sabinus, Oral sustained release tablets of zidovudine using binary blends of natural and synthetic polymers. Biological & Pharmaceutical Bulletin (2010), 33(9), 1561-156.

157. Mao, Chen; Prasanth Chamarthy, Sai; Byrn, Stephen R.; Pinal, Rodolfo, Theoretical and Experimental Considerations on the Enthalpic Relaxation of Organic Glasses using Differential Scanning Calorimetry. Journal of Physical Chemistry B (2010),114(1), 269-279.

158. Lee, Eun Hee; Byrn, Stephen R., Stabilization of metastable flufenamic acid by inclusion of mefenamic acid: solid solution or epilayer., Journal of Pharmaceutical Sciences (2010), 99(9), 4013-4022.

158. Trasi, Niraj S.; Boerrigter, Stephan X. M.; Byrn, Stephen R.; Carvajal, Teresa M., Investigating the effect of dehydration conditions on the compactibility of glucose. International Journal of Pharmaceutics(2011),406(1-2),55-61.

159. Yamauchi, Masahiro; Lee, Eun Hee; Otte, Andrew; Byrn, Stephen R.; Carvajal, M. Teresa, Contrasting the Surface and Bulk Properties of Anhydrate and Dehydrated Hydrate Materials. Crystal Growth & Design(2011),11(3),692-698.

160. Ito, Takanori; Byrn, Stephen; Chen, Xin; Carvajal, M. Teresa. Thermal insight of mechanically activated bile acid powders, International Journal of Pharmaceutics (2011), 420(1), 68-75.

161. Emeje, Martins; Isimi, Christiana; Byrn, Stephen; Fortunak, Joseph; Kunlun, Olobayo; Ofoefule, Sabinus. Extraction and physicochemical characterization of a new polysaccharide obtained from the fresh fruits of Abelmoschus esculentus . Iranian Journal of Pharmaceutical Research (2011), 10(2), 237-246

162. Byrn, Stephen R.; Tishmack, Patrick A.; Milton, Mark J.; Velde, Helgi, Analysis of Two Commercially Available Bortezomib Products: Differences in Assay of Active Agent and Impurity Profile. AAPS PharmSciTech (2011), 12(2), 461-467.

163. Su, Ziyang; Luthra, Suman; Krzyzaniak, Joseph F.; Agra-Kooijman, Dena M.; Kumar, Satyendra; Byrn, Stephen R.; Shalaev, Evgenyi Y. Crystalline, liquid crystalline, and isotropic phases of sodium deoxycholate in water. Journal of Pharmaceutical Sciences (2011), 100(11), 4836-4844.

164. Weber, R.J.K., Benmore, C.J., Tumber, S.K., Tailor, A.N., Rey, C.A., Taylor, L.S., and Byrn, S. R., Acoustic levitation: recent developments and emerging opportunities in biomaterials research, Eur. Biophys. J., (2012) 41, 397-403.

165. Byrn, Stephen R.; Henck, Jan-Olav, Optimizing Physical Form – opportunities and limitations, Drug Discovery Today: Technologies (2012), 9(2), e73-e78.

166. Trasi, Niraj S.; Byrn, Stephen R, Mechanically Induced Amorphization of Drugs: A Study of the Thermal Behavior of Cryomilled Compounds, AAPS PharmSciTech (**2012**), 13(3), 772-784.

167. Lee, Eun Hee; Byrn, Stephen R.; Pinal, Rodolfo, The solution properties of mefenamic acid and a closely related analogue are indistinguishable in polar solvents but significantly different in nonpolar environments, Journal of Pharmaceutical Sciences (**2012**), 101(12), 4529-4539.

168. Fortunak, Joseph MD; Byrn, Stephen R.; Dyson, Brandon; Ekeocha, Zita; Ellison, Tiffany; King, Christopher L.; Kulkarni, Amol A.; Lee, Mindy; Conrad, Chelsea; Thompson, Keeshaloy, An efficient, green chemical synthesis of the malaria drug, piperaquine, Tropical Journal of Pharmaceutical Research (2013), 12(5), 791-798.

169. Lee, Jangmi; Boerrigter, Stephan X. M.; Jung, Young Woo; Byun, Youngjoo; Yuk, Soon Hong; Byrn, Stephen R.; Lee, Eun Hee, Organic vapor sorption method of isostructural solvates and polymorph of tenofovir disoproxil fumarate, European Journal of Pharmaceutical Sciences (2013), 50(3-4), 253-262.

170. Weber, J. K. R.; Benmore, C. J.; Tailor, A. N.; Tumber, S. K.; Neuefeind, J.; Cherry, B.; Yarger, J. L.; Mou, Q.; Weber, W.; Byrn, S. R., A neutron-X-ray, NMR and calorimetric study of glassy Probucol synthesized using containerless techniques, Chemical Physics (2013), 424, 89-92.

171. Benmore, Chris J.; Weber, J. K. R.; Tailor, Amit N.; Cherry, Brian R.; Yarger, Jeffery L.; Mou, Qiushi; Weber, Warner; Neuefeind, Joerg; Byrn, Stephen R., Structural characterization and aging of glassy pharmaceuticals made using acoustic levitation, Journal of Pharmaceutical Sciences (2013), 102(4), 1290-1300.

172. Gurvich Vadim J; Byrn Stephen R, NIPTE: a multi-university partnership supporting academic drug development, Drug Discovery Today (2013), 18(19-20), 916-21.

173. Byrn, Stephen; Futran, Maricio; Thomas, Hayden; Jayjock, Eric; Maron, Nicola; Meyer, Robert F.; Myerson, Allan S.; Thien, Michael P.; Trout, Bernhardt L., Achieving Continuous Manufacturing for Final Dosage Formation: Challenges and How to Meet Them. 2014 Continuous Symposium, May 20-21, Journal of Pharmaceutical Sciences (2015), 104(3), 792-802.

174. Song, Yang; Yang, Xinghao; Chen, Xin; Nie, Haichen; Byrn, Stephen; Lubach, Joseph W., Investigation of Drug-Excipient Interactions in Lapatinib Amorphous Solid Dispersions Using Solid-State NMR Spectroscopy, Molecular Pharmaceutics (2015), Ahead of Print. DOI:10.1021/mp500692a

175. Song, Yang; Zemlyanov, Dmitry; Chen, Xin; Nie, Haichen; Su, Ziyang; Fang, Ke; Yang, Xinghao; Smith, Daniel; Byrn, Stephen; Lubach, Joseph W, Acid-Base Interactions of Polystyrene Sulfonic Acid in Amorphous Solid Dispersions Using a Combined UV/FTIR/XPS/ssNMR Study; Molecular Pharmaceutics (2016), 13(2), 483-492. Language: English, DOI:10.1021/acs.molpharmaceut.5b00708

176. Nie, Haichen; Mo, Huaping; Zhang, Mingtao; Song, Yang; Fang, Ke; Taylor, Lynne S.; Li, Tonglei; Byrn, Stephen R., Investigating the Interaction Pattern and Structural Elements of a Drug-Polymer Complex at the Molecular Level. Molecular Pharmaceutics (2015), 12(7), 2459-2468. Language: English, DOI:10.1021/acs.molpharmaceut.5b00162

177. Penumetcha, Sai Sumana; Byrn, Stephen R.; Morris, Kenneth R., Relaxation Kinetic Study of Eudragit NM30D Film Based on Complex Modulus Formalism, AAPS PharmSciTech (2015), 16(5), 1180-1189.

178. Nie, Haichen; Xu, Wei; Ren, Jie; Taylor, Lynne S.; Marsac, Patrick J.; John, Christopher T.; Byrn, Stephen R., Impact of Metallic Stearates on Disproportionation of Hydrochloride Salts of Weak Bases in Solid-State Formulations, Molecular Pharmaceutics (2016), 13(10), 3541-3552.

179. Song, Yang; Zemlyanov, Dmitry; Chen, Xin; Su, Ziyang; Nie, Haichen; Lubach, Joseph W.; Smith, Daniel; Byrn, Stephen; Pinal, Rodolfo, Acid-base interactions in amorphous solid dispersions of lumefantrine prepared by spray-drying and hot-melt extrusion using X-ray photoelectron spectroscopy International Journal of Pharmaceutics (Amsterdam, Netherlands) (2016), 514(2), 456-464. Language: English, \,DOI:10.1208/s12249- 015-0289-x

180. Benmore, C. J.; Mou, Q.; Benmore, K. J.; Robinson, D. S.; Neuefeind, J.; Ilavsky, J.; Byrn, S. R.; Yarger, J. L., A SAXS-WAXS study of the endothermic transitions in amorphous or supercooled liquid itraconazole Thermochimica Acta (2016), 644, 1-5.

181. Nie, Haichen; Su, Yongchao; Zhang, Mingtao; Song, Yang; Leone, Anthony; Taylor, Lynne S.; Marsac, Patrick J.; Li, Tonglei; Byrn, Stephen, Solid-State Spectroscopic Investigation of Molecular Interactions between Clofazimine and Hypromellose Phthalate in Amorphous Solid Dispersions, Molecular Pharmaceutics (2016), 13(11), 3964-3975.

182. de Araujo, Gabriel L. B.; Zeller, Matthias; Smith, Daniel; Nie, Haichen; Byrn, Stephen R, Unexpected Single Crystal Growth Induced by a Wire and New Crystalline Structures of Lapatinib, Crystal Growth & Design (2016), 16(10), 6122-6130

183. Braun, Doris E.; Nartowski, Karol P.; Khimyak, Yaroslav Z.; Morris, Kenneth R.; Byrn, Stephen R ; Griesser, Ulrich J., Structural Properties, Order-Disorder Phenomena, and Phase Stability of Orotic Acid Crystal Forms, Molecular Pharmaceutics (2016), 13(3), 1012-1029.

184. Byrn, S. R.; Ekeocha, Z.; Clase, K. L., An Education Strategy to Respond to Medicine Inequality in Africa. J. Pharm. Sci. 2017, 106 (7), 1693-1696.

185. de Araujo, G. L. B.; Benmore, C. J.; Byrn, S. R., Local Structure of Ion Pair Interaction in Lapatinib Amorphous Dispersions characterized by Synchrotron X-Ray diffraction and Pair Distribution Function Analysis. Sci. Rep. 2017, 7, 46367.

186. Kalra, A.; Tishmack, P.; Lubach, J. W.; Munson, E. J.; Taylor, L. S.; Byrn, S. R.; Li, T., Impact of Supramolecular Aggregation on the Crystallization Kinetics of Organic Compounds from the Supercooled Liquid State. Mol. Pharmaceutics 2017, 14 (6), 2126-2137.

187. Nie, H.; Byrn, S. R.; Zhou, Q., Stability of pharmaceutical salts in solid oral dosage forms. Drug Dev. Ind. Pharm. 2017, 43 (8), 1215-1228.

188. Nie, H.; Xu, W.; Taylor, L. S.; Marsac, P. J.; Byrn, S. R., Crystalline solid dispersion-a strategy to slowdown salt disproportionation in solid state formulations during storage and wet granulation. Int. J. Pharm. (Amsterdam, Neth.) 2017, 517 (1-2), 203-215.

189.Weber, J. K. R.; Benmore, C. J.; Suthar, K. J.; Tamalonis, A. J.; Alderman, O. L. G.; Sendelbach, S.; Kondev, V.; Yarger, J.; Rey, C. A.; Byrn, S. R., Using containerless methods to develop amorphous pharmaceuticals. Biochim. Biophys. Acta, Gen. Subj. 2017, 1861 (1_Part_B), 3686-3692.

190. Zeller, M.; Barros de Araujo, G. L.; Parker, T.; Singh Rai, A.; Byrn, S. R., A new solvate of afatinib, a specific inhibitor of the ErbB family of tyrosine kinases. Acta Crystallogr., Sect. E: Crystallogr. Commun. 2017, 73 (3), 417-422.

191. Nie, Haichen; Mo, Huaping; Byrn, Stephen R., Investigating the Physicochemical Stability of Highly Purified Darunavir Ethanolate Extracted from PREZISTA Tablets, AAPS PharmSciTech (2018), 19(5), 2407-2417.

192. Boyce, Heather; Smith, Dan; Byrn, Steve; Saluja, Bhawana; Qu, Wen; Gurvich, Vadim J.; Hoag, Stephen W. In Vitro Assessment of Nasal Insufflation of Comminuted Drug Products Designed as Abuse Deterrent Using the Vertical Diffusion Cell, AAPS PharmSciTech (2018), 19(4), 1744-1757.

193. de Araujo, Gabriel L. B.; Ferreira, Fabio Furlan; Bernardes, Carlos E. S.; Sato, Juliana A. P.; Gil, Otavio M.; de Faria, Dalva L. A.; Loebenberg, Raimar; Byrn, Stephen R. ; Ghisleni, Daniela D. M.; Bou-Chacra, Nadia A.; et al, A new thermodynamically favored flubendazole/maleic acid binary crystal form: Structure, energetics, and in silico PBPK model-based investigation, Crystal Growth & Design (2018), 18(4), 2377-2386.

194. Kalra, Arjun; Luner, Paul; Taylor, Lynne S.; Byrn, Stephen R.; Li, Tonglei, Gaining Thermodynamic Insight From Distinct Glass Formation Kinetics of Structurally Similar Organic Compounds, Journal of Pharmaceutical Sciences (Philadelphia, PA, United States) (2018), 107(1), 192-202.

195. Nie, Haichen; Byrn, Stephen R., Edited By:Li, Tonglei; Mattei, Alessandra, Polymorphism and phase transitions, Pharmaceutical Crystals (2019), 169-221.

196. Byrn, Stephen R.; Chen, Xiaoming Sean; Smith, Pamela A., Predictive and Accelerated Formulation Design Using Synchrotron Methods, AAPS PharmSciTech (2019), 20(5), 1-11.

197. Lavan, Monika; Byrn, Stephen R.; Knipp, Gregory, Pediatric Formulations: Knowledge Gaps Limiting the Expedited Preclinical to Clinical Translation in Children, AAPS PharmSciTech (2019), 20(2), 1-7. .

198. Barbosa, E. J.; Gubitoso, M. R.; Bou-Chacra, N. A.; Byrn, S. R.; Carvalho, F. M. S.; Barros de Araujo, G. L., Contribution to the improvement of an oral formulation of niclosamide, an antihelmintic drug candidate for repurposing in SARS-CoV-2 and other viruses. *ChemRxiv* **2020**, 1-7.

199. Boyce, H. J.; Dave, V. S.; Scoggins, M.; Gurvich, V. J.; Smith, D. T.; Byrn, S. R.; Hoag, S. W., Physical Barrier Type Abuse-Deterrent Formulations: Mechanistic Understanding of Sintering-Induced Microstructural Changes in Polyethylene Oxide Placebo Tablets. *AAPS PharmSciTech* **2020,** *21* (3), 86.

200. Byrn, S. R.; Dan, S.; Smith, P. A.; Tian, F.; Zimmerman, A.; Gao, M. Composition with improved dissolution properties. CN111467501A, 2020.

201. Lu, X.; Huang, C.; Li, M.; Skomski, D.; Xu, W.; Yu, L.; Byrn, S. R.; Templeton, A. C.; Su, Y., Molecular Mechanism of Crystalline-to-Amorphous Conversion of Pharmaceutical Solids from 19F Magic Angle Spinning NMR. *J. Phys. Chem. B* **2020,** *124* (25), 5271-5283.

202. Lu, X.; Li, M.; Huang, C.; Lowinger, M. B.; Xu, W.; Yu, L.; Byrn, S. R.; Templeton, A. C.; Su, Y., Atomic-Level Drug Substance and Polymer Interaction in Posaconazole Amorphous Solid Dispersion from Solid-State NMR. *Mol. Pharmaceutics* **2020,** *17* (7), 2585-2598.

203. Lu, X.; Tsutsumi, Y.; Huang, C.; Xu, W.; Byrn, S. R.; Templeton, A. C.; Buevich, A. V.; Amoureux, J.-P.; Su, Y., Molecular packing of pharmaceuticals analyzed with paramagnetic relaxation enhancement and ultrafast magic angle spinning NMR. *Phys. Chem. Chem. Phys.* **2020,** *22* (23), 13160-13170.

204. Okezue, M.; Smith, D.; Zeller, M.; Byrn, S. R.; Smith, P.; Bogandowich-Knipp, S.; Purcell, D. K.; Clase, K. L., Crystal structures of salts of bedaquiline. *Acta Crystallogr., Sect. C: Struct. Chem.* **2020,** *76* (11), 1010-1023.

205. Okezue, M. A.; Clase, K. L.; Okezue, M. A.; Adeyeye, M. C.; Abiola, V. O.; Byrn, S. J., Impact of ISO/IEC 17025 laboratory accreditation in sub-Saharan Africa: a case study. *BMC Health Serv Res* **2020,** *20* (1), 1065.

206. Su, Y.; Lu, X.; Huang, C.; Xu, W.; Byrn, S. R.; Templeton, A. In *Molecular packing of posaconazole in crystalline-to-amorphous conversion*, American Chemical Society: 2020; pp PHYS-0753.

207. Yang, M.; Clase, K. L.; Byrn, S. R., An Analytic Investigation of the Drug Formulation- Based Recalls in the USA: See More Beyond the Literal. *AAPS PharmSciTech* **2020,** *21* (5), 198.

208. Barbosa, E. J., Andrade, M. A. B., Gubitoso, M. R., Bezzon, V. D. N., Smith, P. A., Byrn, S. R., Bou-Chacra, N. A., Carvalho, F. M. S., & de Araujo, G. L. B. (2021). Acoustic levitation and high-resolution synchrotron X-ray powder diffraction: A fast screening approach of niclosamide amorphous solid dispersions [10.1016/j.ijpharm.2021.120611]. Int. J. Pharm. (Amsterdam, Neth.), 602, 120611. https://doi.org/10.1016/j.ijpharm.2021.120611

209. Benmore, C. J., Benmore, S. R., Edwards, A. D., Shrader, C. D., Bhat, M. H., Cherry, B. R., Smith, P., Gozzo, F., Shi, C., Smith, D., Yarger, J. L., Byrn, S. R., & Weber, J. K. R. (2022). A High Energy X-ray Diffraction Study of Amorphous Indomethacin [10.1016/j.xphs.2021.12.003]. J. Pharm. Sci. (Philadelphia, PA, U. S.), Ahead of Print. https://doi.org/10.1016/j.xphs.2021.12.003

210. Benmore, C. J., Benmore, S. R., Edwards, A. D., Shrader, C. D., Bhat, M. H., Cherry, B. R., Yarger, J. L., Smith, P., Gozzo, F., Shi, C., Smith, D., Byrn, S. R., & Weber, J. K. R. (2021). A High Energy X-ray Diffraction Study of Amorphous Indomethacin. J Pharm Sci.

211. Bezzon, V. D. N., Ferreira, F. F., Smith, P., Benmore, C. J., Byrn, S. R., & de Araujo, G. L. B. (2021). Amorphous dispersions of flubendazole in hydroxypropyl methylcellulose: Formulation stability assisted by pair distribution function analysis [10.1016/j.ijpharm.2021.120500]. Int. J. Pharm. (Amsterdam, Neth.), 600, 120500. https://doi.org/10.1016/j.ijpharm.2021.120500

212. Kerstiens, E. A., Clase, K. L., Kerstiens, E. A., Byrn, S. R., Clase, K. L., & Byrn, S. R. (2021). The Identification of Quality Risk Factors for Non-biological Complex Drugs and Epilepsy Drugs Using Statistical Analysis of Formulation-Based Recalls in the USA. AAPS PharmSciTech, 23(1), 19.

213. Lavan, M., Wang, X., McCain, R., Jannasch, A., Cooper, B., Hostetler, S., Byrn, S., & Knipp, G. (2021). Development of a Pediatric Mini-Tablet Formulation for Expedited Preclinical Studies [10.1208/s12249-020-01891-x]. AAPS PharmSciTech, 22(1), 40. https://doi.org/10.1208/s12249-020-01891-x

214. Okezue, M., Bogdanowich-Knipp, S., Smith, D., Zeller, M., Byrn, S., Smith, P., Purcell, D. K., & Clase, K. (2021). Salts and Polymorph Screens for Bedaquiline [10.1208/s12249-021-02106-7]. AAPS PharmSciTech, 22(7), 228. https://doi.org/10.1208/s12249-021-02106-7

215. Yu, D., Seelam, R. R., Zhang, F., Byrn, S. R., & Hoag, S. W. (2021). Evaluation of tableting performance of Poly (ethylene oxide) in abuse-deterrent formulations using compaction simulation studies [10.1016/j.xphs.2021.03.008]. J. Pharm. Sci. (Philadelphia, PA, U. S.), 110(7), 2789-2799. https://doi.org/10.1016/j.xphs.2021.03.008

216. Zeller, M., Bogdanowich-Knipp, S., Smith, P., Purcell, D. K., Okezue, M., Clase, K. L., Okezue, M., Clase, K. L., Smith, D. T., Byrn, S. R., & Byrn, S. R. (2021). Maleate salts of bedaquiline. Acta Crystallogr E Crystallogr Commun, 77(Pt 4), 433-445.

217. Zeller, M., Bogdanowich-Knipp, S., Smith, P., Purcell, D. K., Okezue, M., Smith, D. T., Byrn, S. R., & Clase, K. L. (2021). Maleate salts of bedaquiline [10.1107/s2056989021002991]. Acta Crystallogr., Sect. E: Crystallogr. Commun., 77(4), 433-445. https://doi.org/10.1107/s2056989021002991.

218. Benmore, C.J., et al., *A High Energy X-ray Diffraction Study of Amorphous Indomethacin.* Journal of Pharmaceutical Sciences, 2022. **111**(3): p. 818-824.

219. Ekeigwe, A., et al., *Describing competency requirements for competency-based regulatory sciences education in sub-Saharan Africa–A qualitative systematic review.* Pharmacy Education, 2022. **22**(4): p. 42-62.

220. Kerstiens, E.A., S.R. Byrn, and K.L. Clase, *The Identification of Quality Risk Factors for Non-biological Complex Drugs and Epilepsy Drugs Using Statistical Analysis of Formulation-Based Recalls in the USA.* AAPS PharmSciTech, 2022. **23**: p. 1-9.

221. Okezue, M.A. and S.J. Byrn, *Mechanisms for Improving the Clinical Success of a Low-Water Soluble New Drug Moiety, the Bedaquiline Case Study.* 2022.

222. Okezue, M.A., S.J. Byrn, and K.L. Clase, *Determining the solubilities for benzoate, nicotinate, hydrochloride, and malonate salts of bedaquiline.* International Journal of Pharmaceutics, 2022. **627**: p. 122229.

223. Okezue, M.A., S.J. Byrn, and Z. Ekeocha, *Efforts at building capacity for manufacturing and testing the quality of medicines in Sub-Saharan Africa: Historical evidence from the BIRS programme.* Pharmacy Education, 2022. **22**(1): p. 872-894.

224. Salem, S., et al., *Impact assessment of the variables affecting the drug release and extraction of polyethylene oxide based tablets.* Journal of Drug Delivery Science and Technology, 2022. **71**: p. 103337.

225. Salem, S., D. Smith, and S.R. Byrn, *Degradation Products of the Abuse Deterrent Agent Poly (Ethylene) Oxide Under Thermal Manipulation Conditions.* Available at SSRN 4257827.

**Patents**

1. Pyridines for treating injured mammalian nerve tissue, Borgens; Richard B. (Delphi, IN), Shi; Riyi (West Lafayette, IN), Byrn; Stephen R. (West Lafayette, IN), Smith; Daniel T. (Lafayette, IN), US Patent 8,729,107, Sept. 9,2010.

2. Pyridines for treating injured mammalian nerve tissue, Borgens; Richard B. (Delphi, IN), Shi; Riyi (West Lafayette, IN), Byrn; Stephen R. (West Lafayette, IN), Smith; Daniel T. (Lafayette, IN), US 8,097,638, July 16, 2007.

3. Pyridines for treating injured mammalian nerve tissue, Borgens; Richard B. (Delphi, IN), Shi; Riyi (West Lafayette, IN), Byrn; Stephen R. (West Lafayette, IN), Smith; Daniel T. (Lafayette, IN), US 7,244,748, Dec. 5, 2003.

4. Crystalline forms of [R-(R*,R*)]-2-(4-fluorophenyl)-.beta.,.delta.-dihydroxy-5-(1-methylethyl)- -3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt (2:1), Byrn; Stephen Robert (West Lafayette, IN), Coates; David Andrew (West Lafayette, IN), Gushurst; Karen Sue (Lafayette, IN), Krzyzaniak; Joseph Francis (Pawcatuck, CT), Li; Zheng Jane (Quaker Hill, CT),

Morrison, II; Henry Grant (Lafayette, IN), Park; Aeri (West Lafayette, IN), Vlahova; Petinka Ivanova (Lafayette, IN), US 7,144,915, June 6, 2003.

5. NADH oxidase assay for neoplasia determination, Morr e; D. James (West Lafayette, IN), Byrn; Steven R. (West Lafayette, IN), Crane; Frederick L. (West Lafayette, IN), Morre; Dorothy M. (West Lafayette, IN), US 5,605,810, April 5, 1994.

**Book Chapters**

Solid State Structure of Chiral Organic Pharmaceuticals, Stahly, G.P.; and Byrn, S. R., in Molecular Modeling Applications in Crystallization, 313-345, Allan Myerson, Ed., Cambridge Univ., Press

Structural aspects of polymorphism. Brittain, Harry G.; Byrn, Stephen R. Drugs Pharm. Sci., 95(Polymorphism in Pharmaceutical Solids), 73-124

The solid-state structure of chiral organic pharmaceuticals. Stahly, G. Patrick; Byrn, Stephen R. Mol. Model. Appl. Cryst., 313-345. Editor(s): Myerson, Allan S. Cambridge University Press: Cambridge, UK.(English) 1999.

**Papers Presented or Co-Authored:**

A large number of papers have been presented at various conferences since 1974.

**Invited Lectures, Seminars, and Courses:**

"The Mechanisms of Action of Ion Transporting Antibiotics," DePauw Univ., Greencastle, Indiana, October, 1974.

"The Solid State and Solution Conformational Isomerism of Drugs," Commercial Solvents Corporation, Terre Haute, Indiana, May, 1975.

"Solid State Reactions of Drugs," Indiana State University, Terre Haute, Indiana, April, 1975.

"Desolvations of Organic Molecular Crystals and their Pharmaceutical Applications," Chemistry Department, University of Illinois, Urbana Illinois, November, 1977.

"Desolvations of Organic Molecular Crystals and their Pharmaceutical Applications," Department of Medicinal Chemistry, University of Illinois at the Medical Center, Chicago, Illinois, March, 1978.

"Solid State Reactions of Drugs," Eli Lilly and Co., Indianapolis, Indiana, June, 1979.

"Relationship between the Solid State and Solution Conformation of Drugs," Youngstown State University, Youngstown, Ohio, Oct., 1980.

"Solid State Reactions in Medicinal Chemistry," Rose Polytechnical Institute, March, 1980.

"Solid State NMR Spectra of Drugs," Eli Lilly and Co., June, 1982.

"Solid State Chemistry of Drugs," DePauw University, Greencastle, Indiana, October, 1983.

"Polymorphism and the Solid State Chemistry of Drugs," McNeil Laboratories, Fort Washington, Pennsylvania, January, 1984.

"Structure Elucidation of Natural Products Using X-Ray Crystallography," King Saud University, Riyadh, Saudi Arabia, A series of 4 lectures presented in February, 1984.

"Mode of Action of AMSA," Drug Dynamics Institute, School of Pharmacy, University of Texas, Austin, Texas, May, 1984.

"Solid State Chemistry of Drugs," Eli Lilly-Tippecanoe Labs, May 10, 1985.

"Methods for the Analysis of Drugs," Hewlett Packard Short Course, Purdue University, West Lafayette, Indiana, June 19, 1985.

"Solid State Chemistry of Drugs," Chemistry Department, University of Kentucky, Lexington, Kentucky, October, 1984.

"Chemistry of Drug-DNA Interactions," Phi Lambda Upsilon Lecture, DePauw-Wabash Chapter, DePauw University, Greencastle, Indiana, March 20, l986.

"Desolvation of Drug Crystal Forms" and "Crystallographic Study and Solid State NMR Spectra of Crystalline Drugs," both Seminars presented at Merck-Frosst Pharmaceuticals, Montreal, Canada, May 4-6, l986.

"Solid State Chemistry of Drugs, Desolvation, Oxidation, and Solid State NMR Spectra of Steroid Crystal Forms," Merck Sharp and Dohme Research Laboratories, West Point, Pennsylvania, June l0, l986.

"Solid State Stability of Drug Substances," Burroughs Wellcome Company, Research Triangle Park, North Carolina, October l, l986.

"Solid State Oxidation Reactions," Merck Sharpe and Dohme Research Laboratories, West Point, Pennsylvania, May 8, l987

"Polymorphs and Solvates of Drugs," Ortho Lecture Series, Ortho Pharmaceutical, Raritan, New Jersey, April 22, l987.

"Solid State Chemistry of Drugs," K. N. Trueblood Retirement Symposium, University of California, Los Angeles, California, March 18, 1989.

"Residential School: Polymorphs and Solvates of Drugs," Short Course, Royal Society of Chemistry, University of Bradford, London, June 24-26, 1989.

"Solid State Oxidation Reactions," University of Wisconsin, Madison, Wisconsin, June 12, 1989.

"Solid State Chemistry of Drugs," Land-of-Lakes Conference, Madison, Wisconsin, June 13, 1989.

"Solid State Chemistry of Steroids," Upjohn Company, Kalamazoo, Michigan, November 6, 1989.

"Solid State Chemistry of Drugs," Wyeth-Ayerst Pharmaceuticals, Rouses Point, New York, February 20, 1990.

"Solid State Chemistry of Drugs," Smith Kline Beecham, King of Prussia, Pennsylvania, April 11, 1990.

X-Ray Crystallographic Analysis of Pharmaceuticals," Land of Lakes Conference, Madison, Wisconsin, August 1, 1990.

"Solid State Oxidation Reactions," Pfizer Central Research, Groton, Connecticut, August 18, 1989.

"Solid State Chemistry of Drugs," Glaxo, Inc., Research Triangle Park, North Carolina, August 22, 1990.

"Polymorphs and Solvates of Drugs," Short Course presented to Hoffmann LaRoche, Nutley, New Jersey, September 11 and 12, 1990.

"Stability of Solvated Crystals," Abbott Laboratories, Abbott Park, Illinois, April 17, 1991.

"Powder Diffraction Analysis of Pharmaceuticals," Parke-Davis/Warner Lambert, Holland, Michigan, May 3, 1991.

"Anticancer Drug Design," American Cancer Society, Indianapolis, Indiana, February 25, 1989.

"Polymorphs and Solvates of Drugs," Short Course, Purdue University, June 5-7, 1990.

"Crystal Hydrates and Water in Crystalline Pharmaceuticals," Eino Nelson Conference, Phoenix, Arizona, November 27, 1990.

"Polymorphs and Solvates of Drugs," Burroughs-Wellcome, Inc., Greenville, North Carolina, April 9, 1991.

"Pharmaceutical Solids Short Course," Rhone-Poulenc Rorer, Collegeville, Pennsylvania, January 22-23, 1992.

"Pharmaceutical Solids Short Course," Eli Lilly and Company, Indianapolis, Indiana, February 13-14, 1992.

"Regulatory Issues for Pharmaceutical Solids," Merck Research Laboratories, West Point, Pennsylvania, February 28, 1992.

"Pharmaceutical Solids Short Course," Sandoz Pharmaceutical, East Hanover, New Jersey, March 2-3, 1992.

"Pharmaceutical Solids Short Course," Meadowlands Hilton, Seacacus, New Jersey, April 21-22, 1992.

"Pharmaceutical Solids Short Course," UNIGOV, University of Puerto Rico, San Juan, Puerto Rico, April 30-May 1, 1992.

"Pharmaceutical Solids Short Course," Abbott Laboratories, Chicago, Illinois, May 15, 1992

"Pharmaceutical Solids Short Course," Sterling, Inc., Renseleaar, NY, June 4-5, 1992

"Residential School: Polymorphs and Solvates of Drugs," Short Course, Royal Society of Chemistry, University of Bradford, London, July, 27-29, 1992.

"Pharmaceutical Solids Short Course," Burroughs Wellcome, Greenville, NC, August 11-12, 1992

"Pharmaceutical Solids Short Course," Washington Marriott, Washington, DC, October 27-28, 1992

"Polymorphs and Solvates Short Course," AAPS Short Course, San Antonio, TX, November 15, 1992

"Drug-Excipient Interactions in the Solid State," UNIGOV Conference on Excipients, San Juan, PR, Jan. 28, 1993

"Pharmaceutical Solids Short Course," Rhône-Poulenc Rorer, Paris, France, Feb. 9-10, 1993

"Pharmaceutical Solids Short Course," Meadowlands Hilton, Secaucus, NJ, April 27-30, 1993

"Pharmaceutical Solids Short Course," Syntex, Inc., Palo Alto, CA, May 6-7, 1993

"Mobility in Pharmaceutical Solids," G.D. Searle, Chicago, Illinois, May 12, 1993

"Solid State Chemistry of Drugs," Parke-Davis Warner/Lambert, Morris Plains, NJ, June 21, 1993

"Pharmaceutical Solids Short Course," Washington Marriott, Washington D.C., September 30, 1993

"Solid-State Pharmaceutical Chemistry," PR&D Building Dedication, Merck Research Laboratories, West Point, PA, October 8, 1993

"AIDS Research at Purdue University," Northeast Missouri State University, Kirksville, MO December 7, 1993.

"Mobility in Pharmaceutical Solids," Hoffmann-LaRoche, Nutley, NJ December 9, 1993.

"Solid State Chemistry of Drugs," Parke-Davis Warner/Lambert, Holland, MI, February 24, 1994.

"Mobility in Pharmaceutical Solids," Pfizer Central Research, Groton, CT, February 9, 1994.

"Solid State Pharmaceutical Chemistry," University of Minnesota, Minneapolis, MN, April 4, 1994.

"Pharmaceutical Solids Short Course," Pfizer, Inc., Groton, CT, April 11-12, 1994.

"Pharmaceutical Solids Short Course," Meadowlands Hilton, Secaucus, NJ, April 27-30, 1994.

"Pharmaceutical Solids Short Course," Geneva, Pharmaceuticals, Broomfield, CO, May 4-5, 1994.

"Pharmaceutical Solids Short Course," Crystal City Marriott, Washington, D.C., October 5-7, 1994.

"Instrumental Methods of Characterizing Bulk Drug Substances" Pharmaceutical Seminars, Wilmington, N.C., June, 1994

“Pharmaceutical Solids, “ R.W. Johnson, August 10, 1995.

“Pharmaceutical Solids, “ Upjohn Co., December 7, 1995.

"Pharmaceutical Solids Short Course," Crystal City Marriott, Washington, D.C., April, 1995.

“Solid State Chemistry of Drugs, “ Syntex Chemicals, Inc., Boulder, CO, February 2, 1996

“Intersection of Laws, Regulations, and Scientific Principles,” Burkett Lectures, DePauw University, Greencastle, IN April 2, 1996.

“Organic Solid State Chemistry and Pharmaceutical Materials Science,” Burkett Lectures, DePauw University, Greencastle, IN April 2, 1996.

"Pharmaceutical Solids Short Course," Crystal City Marriott, Washington, D.C., April 30-May 2, 1996.

“Practical Consequences of Polymorphism,” McNeil Consumer Products, Ft. Washington, PA May 7, 1996.

“Practical Consequences of Polymorphism,” Biogen, Cambridge MA, June 12, 1996.

“Practical Consequences of Polymorphism, “Genentech, S. San Francisco, CA, June 19, 1996.

"Pharmaceutical Solids Short Course," Crystal City Marriott, Washington, D.C., April 28 -May 1, 1998.

“Pharmaceutical Solids,” Short Course at the DuPont-Merck, June 12-13, 1997.

“Pharmaceutical Solids,” Short Course at the FDA, September 29, 1997.

"Pharmaceutical Solids Short Course," Crystal City Marriott, Washington, D.C., April 29-May 1, 1998.

“Pharmaceutical Solids,” Proctor and Gamble Pharmaceuticals, Norwich, N.Y., July 27-28, 1998

“Pharmaceutical Solids Short Course,” Sanofi Pharma, September 21-23, 1998

“Pharmaceutical Solids Short Course,” Novartis, Feb. 4-5, 1999

“CAMP Technologies, J&J, Spring House,” PA April 13-15, 1999

“Pharmaceutical Solids, SSCI Course,” Washington, DC, April 28-30, 1999

"Solid-state Chemistry of Drugs and Analysis," University of Michigan, College of Pharmacy and Engineering, Ann Arbor, MI 2-10-00.

"Solid-state Chemistry of Drugs," University of Minnesota, College of Pharmacy, 3-30-00.

"Polymorphism and Solid-state Chemistry of Drugs," Ball State University, Chemistry Department, Muncie, IN 11-11-99.

"Particle Formation and Crystallization of Pharmaceuticals," London, England and Crystal City, VA, June and Sept 9-10. 1999

"Pharmaceutical Solids Short Course," Roche, August 12-13, 1999

"Pharmaceutical Solids Short Course," Searle, October 10-13, 1999

"Pharmaceutical Solids Short Course," Warner-Lambert, November 1-3, 1999

"Pharmaceutical Solids Short Course," Warner-Lambert, Feb. 23-25, 2000

"Pharmaceutical Solids Short Course," Pfizer, March 20-22, 2000

"Pharmaceutical Solids," SSCI Course, Washington, DC, May 9-11, 2000

"Pharmaceutical Solids," SSCI Course, Fremont, CA, May 23-25, 2000

"Pharmaceutical Solids," SSCI Course, J&J, July 29-31, 2000.

"Pharmaceutical Materials Science and Research," AAPS Head's Meeting, Indianapolis, IN, October 27, 2000.

"Dimensions of Pharmaceutical Solids," IIT Seminar, November, 2000.

"Pharmaceutical Solids," SSCI Course, Schering, May, 2001.

"Pharmaceutical Solids," SSCI Course, Washington, DC, May 2001.

"Pharmaceutical Solids," SSCI Course, Pfizer, May, 2001.

"Six Dimensions of Pharmaceutical Solids," Wyeth Ayerst, January 2001.

"Polymorphism and Stability of Drugs," Univ. of Kentucky, February 7, 2001.

"Pharmaceutical Solids, SSCI Course," Washington, DC, May 8-10, 2001

"New Technologies for Process Analytical Technologies," FDA, Washington, DC, April 1, 2002.

"PAT," Watson Pharmaceuticals, Corona, CA, March 3-4, 2003

"Pharmaceutical Solids, SSCI Course," Washington, DC, May 9-11, 2002

"Pharmaceutical Solids, SSCI Course," Washington, DC, May 10-12, 2003

"Solid State Chemistry of Biologicals," SSCI Course, South San Francisco, Nov. 16-17, 2003

"Pharmaceutical Solids, SSCI Course," Washington, DC, May 5-7, 2004

"PAT: Achieving Mechanistic Understanding through Solid State Chemistry," SSCI Short Course, Princeton, NJ, September, 2004

"Midwest Organic Solid State Chemistry Symposium" June 2-4, 2005, Purdue University.

"Pharmaceutical Solids, SSCI Course," Washington, DC, May 9-11, 2005

"Biological Solids," South San Francisco, CA, February 15-16, 2005

"Pharmaceutical Solids, SSCI Course," Washington, DC, March 29-31, 2006.

"Pharmaceutical Solids, SSCI Course," Merck and Co., West Point, PA, September 16-17, 2006.

"Biopharmaceutical Solids, Aptuit/SSCI Course," San Francisco, CA, February, 27-28, 2007.

"Pharmaceutical Solids, SSCI Course," Washington, DC, April 10-12, 2007.

"Pharmaceutical Solids, SSCI Course," Washington, DC, April 8-10, 2008.

"Pharmaceutical Solids, SSCI Course," San Francisco, CA, May 14-15, 2008.

"Processing and Formulation Approaches for Improving the Apparent Solubility Controlled Release, Glatt Controlled Release Symposium, Sept. 18-20, 2007, Mahwah, NJ.

"Solid State Properties in Drug Development," Howard University, Washington, DC, Sept. 10, 2007.

"Pharmaceutical Solids, SSCI Course," Washington, DC, April 22-24, 2008.

"Forced Degradation Testing To Improve Stability Prediction and Reduce Time to Market", Forced Degradation of Small Molecules Conference, Philadelphia, PA, February 25-27, 2008

"Solid Phase Characterization Short Course," EAS, Nov. 11, 2008

"Pharmaceutical Solids, SSCI Course," Washington, DC, April 21-23, 2009.

"Pharmaceutical Solids, SSCI Course," San Francisco, CA, May 13-14, 2009.

"Drug Discovery", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, March 17 - 28, 2008

"Drug Development", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, December 1-12, 2008

"Drug Development", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, May 18-29, 2009

"Pharmaceutical Manufacturing," Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, August 3-14, 2009.

"Drug Discovery", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, March 17 - 28, 2010

"Pharmaceutical Solids, SSCI Course," Washington, DC, April 13-15, 2010.

"Drug Development", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, March 10-19, 2010

"Physical Characterization and Methods of Analysis", Short Course," EAS, Nov. 14, 2010

"Drug Development", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, March 14-25, 2011

"Physical Characterization and Methods of Analysis", Short Course," EAS, Nov. 12-13, 2011

"Sustainable Medicines in Africa," University of Kansas, Oct. 10, 2011

"Drug Development", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, March 14-25, 2011

"Manufacturing", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, August 8-19, 2011

"Documents", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, March 5-16, 2012

"Drug Development", Kilimanjaro School of Pharmacy/St. Luke Foundation Course, Moshi, Tanzania, August 6-17, 2012

"Drug Registration: US FDA Approaches to Reviewing Generic Drug Applications and PEPFAR Reviews." Short course taught by US FDA, Kilimanjaro School of Pharmacy, Purdue University, and Howard University, Moshi, Tanzania , Sept. 24-28, 2012.

"Pharmaceutical Solids," SSCI Short Course, Chicago, IL, Oct. 18-19, 2012

"Pharmaceutical Solids," EAS Short Course, Somerset, NJ, November 4, 2013

"Solid State Properties of Pharmaceutical Materials", Eastern Analytical Symposium, Sommerset, NJ, Nov. 12 and 13, 2015

"Molecular Structure of Medicines," Wagner Lecture, University of Michigan, Sept. 26, 2016.

"Solid State Chemistry of Drugs Impact and Regulatory Awareness," Short Course, Bangkok, Thailand, August 11, 2017.

"Pharmaceutical Solids," EAS Short Course, Somerset, NJ, November 11, 2018

**Invited Symposium Talks at National or International Meetings:**

"The Purdue BS-MS Program," AACP Meeting, Boston, Massachusetts, July, 1980.

"Polymorphism and the Solid State Chemistry of Drugs," FACSS Meeting, Philadelphia, Pennsylvania, September, 1983.

"CP/MAS Spectra of Drugs, A New Method for the Investigation of Polymorphs and Solvates," 25th Annual Medicinal Chemistry Symposium, SUNY Buffalo, Buffalo, New York, June 11-14, 1984.

"Polymorphism and the Solid State Chemistry of Drugs," Eastern Analytical Symposium, New York, New York, November 15, 1984.

"Structure-Reactivity Correlations in Crystalline Solids," 132nd Annual A.Ph.A. Meeting, San Antonio, Texas, February 19, 1985.

"Solid State Chemistry of Drugs," A.Ph.A. Acad. Pharm. Sci., Short Course on Materials Characterization, San Francisco, California, March 16, 1986.

"Solid State Chemistry of Polymorphs, Solvates, and Metastable Crystal Forms of Drugs," North Eastern Regional Pharmaceutics Association Seventh Annual Meeting, New Haven, Connecticut, June 27, 1986.

"Correlation of Crystal Structure and Solid State NMR Spectra of Steroid Polymorphs," 44th Pittsburgh Diffraction Conference, Pittsburgh, Pennsylvania, October 29-31, 1986.

"Polymorphism of Drugs," Annual Meeting of the American Crystallographic Association, University of Texas, Austin, Texas, March 15-20, 1987.

"Overview - Current Status of Basic Research in Pharmaceutical Solids," Second Annual Meeting, American Association of Pharmaceutical Sciences, Boston, Massachusetts, June 7-12, 1987.

"X-ray Crystallography and Solid-State NMR," American Crystallographic Association Symposium, Philadelphia, Pennsylvania, June 1988.

"Hepa Filtration and Biosafety Training of Pharmacy Students," Biomedical Safety Conference, Indianapolis, Indiana, June l989.

"Design of Anti-AIDS Drugs," 17th International Symposium of the Controlled Release Society, Reno, Nevada, July 22-25, 1990.

"Structure and Stability of Crystal Solvates," American Association of Pharmaceutical Scientists, Las Vegas, Nevada, November 6, 1990.

"Structure and Behavior of Crystal Hydrates," Eino Nelson Conference, Phoenix, Arizona, November 27, 1990.

"Structure and Mobility of Polymorphs and Solvates of Pharmaceuticals," 4th Computational Methods in Chemical Design, Kloster Irsee, Germany, May 15-20, 1994.

"Solid State Chemical Instability: Mechanistic and Kinetic Issues" 36th Annual International Industrial Pharmaceutical Research Conference, " Merrimac, Wisconsin, June 6-10, 1994.

"Solid State Pharmaceutical Chemistry: Applications of Solid State NMR," PharmAnalysis Conference, Atlantic City, NJ, June 21, 1994.

"Solid State Pharmaceutical Chemistry," 25th Meeting, Fine Particle Society and Second International Conference, New Brunswick, NJ, July 26, 1994.

“Solid State Pharmaceutical Chemistry,” Am. Cryst. Assoc., July, 27, 1995, Montreal, Canada

“Chemical Reactions in Amorphous or Disordered Pharmaceutical Solids,” Fine Particle Society, Chicago, IL, August 23, 1995

“Color Dimorphism from 1905 To 1995,” COGM International Meeting, Washington, DC, August 30, 1995

“Practical Consequences of Polymorphism,” FDA-AAPS Workshop on Polymorphism, Washington, D.C., February 26-28, 1996

“New Developments in Solid State NMR,” AAPS-USP Meeting, Washington, D.C., April 25-6, 1996.

“Solid State NMR Spectra of Drugs, Eastern Analytical Symposium, Somerset, N.J., Nov. 8, 1996

“Solid-state Chemical Reactions of Drugs,” Higuchi Conference, Lake of the Ozarks, Mo., March 9-11, 1997.

“Assessment: Impact of Bulk Drug Manufacturing Changes on Physical Properties”, AAPS-FDA BACPAC Conference, Washington D.C., March 25, 1997

“Practical Consequences of Polymorphism,” ACT Meeting, St. Louis, Mo., April 7-9, 1997.

“Characterization of Polymorphic Behavior: Research and Regulatory Perspective,” AAPS Eastern Regional Meeting, New Brunswick, N.J., June 9-10,1997.

"Overview - What is Polymorphism and How Important is it?" British Pharmaceutical Conference, Scarborough England, September 18, 1997.

"Chemical Reactivity in the Solid State," AAPS National Meeting, Boston, Mass., Nov. 2-6, 1997

"Solid State Chemistry – Regulations and Reactions" MSI International Symposium, San Diego, CA, February 18-20, 1998

"Physical Transformations of Solvated Pharmaceuticals," Royal Society of Chemistry National Meeting, Polymorphism Symposium, Durham, England, April 7, 1998

"Stability of Solid Pharmaceuticals," AAPS Western Regional Meeting, South San Francisco, CA. June 1, 1998

"Crystallization and Polymorphism Issues in Controlled Release Dosage Forms," Organized and presented at a one day short course, Controlled Release Society International Meeting, Las Vegas, NV., June 25, 1998.

"BACPAC," World Pharm Conference, Philadelphia, PA, Sept 22, 1998

"BACPAC and PQRI," DIA Conference, Washington, D.C., Nov. 9, 1998

"PQRI", AAPS National Meeting, San Francisco, CA, Nov. 17, 1999

"Energy-temperature Diagrams," PhaTA4, Karlsruhe, Germany, March 24, 1999

"BACPAC, An Update, SUPAC Conference, Washington, DC, 5-4-99

"BACPAC, Bulk Active Post Approval Changes," World Pharm., Philadelphia, PA, 10-28-00.

"Transformation During Processing," AAPS National Meeting, New Orleans, LA 11-15-99

"PQRI, Drug Substances Technical Committee," AAPS National Meeting, New Orleans, LA 11-15-99

"Impurities and Stability of Pharmaceuticals," GMP-API Course, Univ. of Wisconsin Continuing Ed., Jan 20, 2000 and May 19, 2000.

"Crystallization of Pharmaceuticals," Alun Bowen Lecture, British Crystallographic Association Meeting, April 4, 2000, Edinburgh, Scotland

"Computational Approaches to Solid State Chemistry," Millennium Pharmaceutical Sciences Meeting, San Francisco, CA April 18, 2000

"Chemical Stability of Pharmaceuticals," Land of Lakes Conference, Devils Lake, WI, June, 2000.

"Solid State NMR of Pharmaceuticals," SMASH NMR Conference, Argonne, IL July 16, 2000.

"Polymorphism," Land of Lakes Analytical Conference, Devils Lake, WI, July 31, 2000.

"Fundamentals of Solid State Reactions," AAPS National Meeting, Indianapolis, IN, Oct. 26, 2000.

"NIR and LIF Methods of Monitoring Blend Homogeneity," AAPS National Meeting, Indianapolis, IN 2000.

"Strategies for Metastable Phases," AAPS Congress of Americas Short Course, March 2000.

"Implications of Solid State Chemistry for Process Development," Rhodia International Conference on Process Development, Amelia Island, FL, April 2001

"Raman Mapping and Physical Transformations," EAS, September 2001, Atlantic City, NJ

"Using Crystal Engineering to Predict Stability and Reduce Time to Market," Higuchi Research Seminar, May 2001, Lawrence, KA.

Polymorphism & Crystallization Conference, Chairperson and Presenter on Regulatory Aspects, Philadelphia, PA June 20-21, 2002.

"Crystallization and Solid State Chemistry of Pharmaceuticals", Aminoff Symposium, Royal Academy of Sciences, Stockholm, Sweden, September 12, 2002.

"Validation of Process Analytical Technologies", IVT PAT Conference, Gaithersberg, MD, Oct. 24, 2002

"Engineering Sameness: Polymorphism, Crystallization, and Stability of Solid Pharmaceuticals", AIChE Plenary Lecture, AIChE National Meeting, Indianapolis, IN, November 4, 2002

"Solid State Analysis of API in Drug Product," AAPS National Meeting, November 6, 2002

"Validation of NIR Methods for the Pharmaceutical Industry," AAPS National Meeting, November 6, 2002

"Achieving Sameness, USP, Washington, DC, December 18, 2002.

"Strategies for Incorporating NIR into PAT, " IIR Conference, Washington, DC, Feb 4-6, 2003.

"Overview of Particle Manufacture and Blending," Particle Size analysis Workshop, AAPS, April 30, 2003.

"Reactivity of Polymorphs, Predicting Stability," ACS Prospectives Conference, Tampa, FL Feb 23, 2003

"Regulatory Aspects of Polymorphism," APV Course, Bonn, Germany, May 12, 2003

"Approaches to PAT using In-line Sensors," PAT Summit, Washington, DC, September 29, 2003

"Solid State Characterization Technologies for Online Analysis," AAPS National Meeting, Salt Lake City, UT, October 30, 2003

"National GMP Curriculum, "AAPS National Meeting, Salt Lake City, UT, October 28, 2003

Enz Lectures, University of Kansas, August, 2004

"Solid State Chemistry of Amorphous Materials," ACS Prospectives Symposium, Feb 8-11, 2004

"Polymorphism and Pharmaceuticals," Stephen R. Byrn, IUCR Intl. School of Crystallography, Diversity Amidst Similarity, Erice, Italy

"Strategies to Improve Solubility Using Amorphous Materials and Co-crystals," Barnett Improving Solubility Conference, Philadelphia, PA, June 3, 2005.

"Polymorphs of API and Implications in Drug Development," CVG Conference, Toronto, CA, Sept. 27, 2004

"Implementing Quality by Design," IIR PAT Conference, Princeton, NJ, Dec. 13, 2004.

"Novel Approaches to Characterization," AAPS National Meeting, Baltimore, MD, November 2005.

"Busse Lectures" (1. Solid State Pharmaceutical Chemistry; 2. Regulated Pharmaceutical Industry in 2010), University of Wisconsin, Madison, Wisconsin.

"Achieving Mechanistic Understanding through Solid State Chemistry," PAT Workshop, J. Liang and S. Byrn, PAT Conference, June 14-17, 2005, Philadelphia, PA.

"Regulatory Applications of Patent-Derived Analytical Methods," PITTCON, March 4, 2005, Orlando FL,

"Using PAT to Reduce Time to Market" Academic and Industrial Research in PAT, Wyeth Scientific Symposium, Pearl River, NY, Feb. 27, 2005.

"PAT Process Understanding and Control of APIs" PAT Workshop, J. Liang and S. Byrn, PAT Conference, June 14-17, 2005, Philadelphia, PA.

"Novel Approaches to Characterization. Accelerating the Drug Development Process" AAPS National Meeting, November 11 2004, Baltimore, MD.

"Polymorphs in API, Implications for Drug Development", CVG Meeting, Toronto, CA, Sept. 27-28, 2005.

"Building a Start-up Knowledge Based Company" ACS National Meeting, August 2004, Philadelphia, PA.

"Design and Characterization of Pharmaceutical Solids for Quality Product Development, Strategies for the 21st Century," Keynote Lecture, Stephen R. Byrn, Ph. D., Department of Industrial and Physical Pharmacy, Purdue University and SSCI, Inc. West Lafayette, Indiana, Land of Lakes 48th Conference, Merrimac Wisconsin, June 2006.

"Physical Characterization of Pharmaceutical Solids,"NIST Meeting on Organic Materials, NIST, Rockville, MD, April 5-7, 2006.

"What does this all mean to a Formulator," AAPS National Meeting, Nashville, TN, Nov. 6-11, 2006.

"New Opportunities in Solid State Characterization", British Pharmaceutical Conference, Manchester, England, September 24-28, 2005.

"Using PAT to Understand Process and Reduce Time to Market and Speed Drug Development while Avoiding Regulatory Problems," Bioanalytical Testing World Congress, Philadelphia, PA, and September 19-21, 2006.

"Science-Based Product Management and PAT", Global Manufacturing Summit, September 7-9, 2005, Atlanta, GA.

"Solid State Strategies for Improving Solubility", Water-Insoluble Drug Delivery Course, Park Hyatt Hotel, Philadelphia, PA, July 18, 2005.

"Implication of Polymorphism for Formulation Design", Formulation Development Meeting, Philadelphia, PA, July 26-27, 2006

"Improving Drug Development Via Crystallization And Crystal Growth." Edinburg, Scotland, Sept 10-12, 2006.

"Physical Stability in the Solid State", Stephen R. Byrn, AAPS Workshop on Pharmaceutical Stability, September 10-12, Bethesda, MD, 2006.

"Quality by "Design and PAT", AICHE National Meeting, Salt Lake City Utah, November 5, 2007.

Chairman Polymorphism and Crystallization Scientific Forum, IQPC, December 3-5, Philadelphia, PA. Presented Lead-off Talk entitled: "Designing Optimized Formulations Utilizing Polymorphs/Cocrystals/Amorphous Forms within a Preclinical Timeframe."

**"**Leverage Forced Degradation Testing To Improve Stability Prediction and Reduce Time to Market", Forced Degradation of Small Molecules, February 25-27, 2008

"Strategies for Preparation and Manufacture of Polymer-based Nanoparticulate Formulations", Bio-Nano Conference, Hyderbad India, March 13-14, 2008.

"Quality by design and Process Analytical Technology for Pharmaceutical Manufacturing in the 21st Century", Bio-Nano Conference, Hyderbad India, March 13-14, 2008.

"Molecules to Medicines: Bringing Drugs to Market Following GMP. Green Chemistry and Production of Essential Medicines in Developing Countries", March 18-20, 2008, Abuja Nigeria

"A Model for Education and Pharmaceutical Manufacturing in Africa, Green Chemistry and Production of Essential Medicines in Developing Countries", March 18-20, 2008, Abuja Nigeria

"Understanding Additive Effects on Crystallization, Polymorphic Transformation and Solubility" ACS Award in Separations Science and Technology Symposium, ACS National Meeting, New Orleans, LA, April 7, 2008

"Fast to IND with Quality by Design", ISPE International Conference, Boca Raton, FL, Oct. 28, 2008.

"Utilizing Amorphous Dispersions to Reduce Time to IND", AAPS International Meeting, Atlanta, GA, Nov. 23, 2008.

"A QbD Solubility Enhancement Platforms for Fast Drug Development Abstract", Keynote lecture at the Indo-US Bilateral Workshop on Pharmaceutical Cocrystals and Polymorphs, Mysore, India, February 8 to 11, 2009

"Accelerating Proof of Concept Using Solid State Chemistry", PGSRM Conference, Purdue University, June 25-27,

"Sustainable Medicines in Africa", Swintowsky Distinguished Lecture, University of Kentucky, Lectington, KY, Sept. 24, 2009

"Accelerating Proof of Concept", Swintowsky Distinguished Lecture, University of Kentucky, Lectington, KY, Sept. 25, 2009

"Accelerating Proof of Concept Using Solid State Chemistry," David Grant Award Lecture, AAPS, Sept 11, 2009, Los Angeles, CA.

"Accelerating Translational/Clinical Research using Solid State Chemistry", David Grant Symposium, University of Minnesota, June 2, 2010.

"Strategies for Novel Pediatric Formulations," Peck Symposium, Purdue University, October 14, 2010.

"Solid-state Chemistry of Biopharmaceuticals: Fundamental Issues and Study Approaches", Arden House AAPS Conference, West Point, NY, March 10, 2011

"Sustainable Medicine Program in Tanzania and East Africa" AAPS Indianapolis-Cincinnati Discussion Group, January 27, 2011

Sustainable Medicines in Africa, AAPS National Meeting, New Orleans, LA, Nov. 15, 2011

Sustainable Medicines in Africa FACCS National Meeting, Reno, NV, Oct. 5, 2011

Design and Characterization of Drug Substance Solid Form for Quality Formulation Development, Strategies for the 21st Century, Land of Lakes Conference, Devil's Lake, Wisconsin, June 11-15, 2012.

Accelerating Proof of Concept Using Solid State Chemistry, Aptuit Conference on Early Drug Development, Florence, Italy, May 15, 2012.

Enhancing Drug Bioavailability and Solubility, Stephen Byrn, Boston Solubility and Bioavailability Conference, January 22, 2013

Sustainable Medicines in Africa, Pittcon, Philadelphia, PA, March 19, 2013

Business and Clinical Rationale for Development of Fixed Dose Combination Products, Land of Lakes Conference on FDC Drugs, Madison, WI, June 3, 2014

Enhancing Drug Bioavailability and Solubility, Stephen Byrn, California Solubility and Bioavailability Conference, June 18, 2013

Framing the Key Properties that Must be Optimized in Drug Molecules in Order to have a Drug Product, AAPS National Meeting, San Antonio, November 12, 2013

Winning the Race: Using the Right Strategies for Phase and Formulation to Rapidly Achieve Clinical Entry, AAPS National Meeting, San Antonio, November 13, 2014

Introducing Levitation Technology for the Production of Amorphous Drugs, Boston Solubility Project, ex Pharma, Boston Mass. Jan. 27-28, 2014.

Structure and Analysis of Amorphous Solids, ICDD Meeting, Hyderabad, India, August, 18, 2017

Regulatory Science of Solid State Chemistry, IUCr Crystallography Meeting, Hyderabad, India, August, 19, 2017.

Pharmaceutical Synchrotron XRPD Workshop, 6-8 May, 2018, Purdue University, Co-organizer. International Synchrotron meeting.

Structure and Analysis of Amorphous Dispersions, Stephen Byrn, Chris Benmore, Gabriel deAraujo, Amrinder Rai, Purdue University, West Lafayette, IN and Argonne National

Laboratory, Chicago, IL. Presentation at Pharmaceutical Synchrotron XRPD Workshop, 6-8 May, 2018, Purdue University.

Synchrotron X-Ray Diffraction and Pair Distribution Function Analysis of Drug/Polymer Dispersions: A Comparison of Subtraction Techniques to Isolate Intra-and Intermolecular Interactions, Pamela Smith[a], Stephen R. Byrn[a], Gabriel L.B. de Araujo[b], Chris J. Benmore[c]a) Improved Pharma, b) Department of Pharmacy, University of Sao Paulo, c) X-ray Science Division, Advanced Photon Source, Argonne National Laboratory PPXRD-16 and SS-XRPD-2 at the Swiss National Light Source, Villagen, Switzerland, 9 May 2019 to 12 May 2019.

Co-oganized and chaired several sessions of the PPXRD-16 and SS-XRPD-2 at the Swiss National Light Source, Villagen, Switzerland, 9 May 2019 to 12 May 2019.

Continuity of Solids between Amorphous and Crystalline States, Stephen Byrn and Gabriel De Araujo, Purdue University, Chris Benmore, Argonne Laboratories, American Crystallographic Association, National Meeting, American Crystallographic Association Meeting, Cincinnati, Ohio, July 2019.

**Principal Investigator on Grants:**

"Conformational Isomerism in the Solid State and in Solution," Stephen R. Byrn, Am. Chem. Soc. Starter Grant #2687-G1, $7,500, 7-1-72 to 6-30-76.

"The Structures of Ion Transporting Antibiotics in the Solid State and in Solution," Stephen R. Byrn, Cottrell Research Grant from the Research Corporation, $5,345, 1-1-73 to 12-31-75.

"The Interaction of Intercalating Agents with Dideoxynucleotides-Daunomycin," Stephen R. Byrn, Purdue Cancer Committee Grant, $6,000, 1-1-74 to 12-31-75.

"Structural Studies of Physiologically Active Agents," Stephen R. Byrn, NIH Grant #ES00929, $91,076 Direct Costs, 5-1-74 to 4-30-77.

"Solid State Reactions in Medicinal Chemistry," Stephen R. Byrn, NIH Grant #GM21174, $75,000 Direct Costs, 6-1-74 to 5-31-77.

"Structural Studies of Physiologically Active Agents," Stephen R. Byrn, NIH Grant #ES00929, $127,500 Direct Costs, 5-1-77 to 4-30-80.

"Conformational of Pyridoxal Schiff's Bases in the Presence and Absence of Enzymes," Stephen R. Byrn and M.D. Tsai, David Ross Grant, $8,400, 3-1-76 to 2-28-78.

"Solid State Reactions in Medicinal Chemistry," Stephen R. Byrn, NIH Grant #GM21174, $126,000 Direct Costs, 9-1-78 to 8-31-81.

"Molecular Pharmacology of 9-Aminoacridine Antitumor Agents," Purdue Cancer Committee, $5,000, 7-1-80 to 12-31-82.

"Mechanism of Degradation of Moxalactam and Related Compounds," Eli Lilly and Company, 1-1-81 to 12-31-81, $50,000 Total Costs.

"Acridine-DNA Interactions," Part of a Program Project Grant from the National Cancer Institute, W.M. Baird Project Director, ca. $100,000 Direct Costs for 9-1-81 to 6-30-84.

"Solid State Chemistry of Drugs," Eli Lilly and Company, 1-1-82 to 12-31-82, $46,000 Direct Costs.

"Mode of Action of Mutagenic Drugs," NIH Grant #GM29175, 3-1-83 to 2-28- 86, $181,000 Direct Costs.

"Solid State Chemistry of Insulin, Nabilone and Cefaclor," Eli Lilly and Company, 1-1-83 to 12-31-83, $34,000 Direct Costs.

"Solid State Chemistry of Insulin and Ceftazidine," Eli Lilly and Company, 5-1-85 to 4-30-86, $5,000 Total Costs, (0593-57-13335), D.L. Smith Co-PI.

"Polymorphism and the Bioavailability of Drugs," NIH Grant #GM34520, 12-1-84 to 11-30-85, $180,000 Direct Costs.

"National Cooperative Drug Discovery Group for the Treatment of AIDS - Synthetic Approach," NIH U0l AI25712, 9-1-87 to 8-31-90, $1,046,000 Direct Costs for three years.

"Anti-HIV (AIDS) Agents Targeted to the RNA Template," NIH Grant #GM24289, 4-1-88 to 3-31-91, $228,000 for three years.

"Solid State Chemistry of Drugs," Grant from Merck and Company, 1988-1990, $50,000.

"Center for AIDS Research," $3,100,000 direct cost, approximately $4,600,000 total costs. September 30, l988 - March 1, 1994.

"Chemical Pharmacology Training Grant," 7-1-90 to 6-30-95, approximately $900,000 Direct Costs for 5 years.

"Chemical Pharmacology Training Grant," 7-1-95 to 6-30-97, approximately $1,200,000 Direct Costs for 5 years.

"Effect of Water on the Molecular Mobility of Pharmaceuticals," Purdue-Wisconsin Joint Project, S. R. Byrn and G. Zografi. Supported by Merck, Pfizer, Sandoz, Glaxo, Upjohn, Boehringer, Bristol-Myers Squibb, and Syntex 1991-1997, approximately $115,000 per year.

“Crystal Growth and Nucleation During Drying,” 9-1-95 to 8-31-97, $50,000. NSF Pharmaceutical Processing Center, Purdue University, West Lafayette, IN

“CAMP - Consortium for the Advancement of Manufacturing in Pharmacy” 12-1-96 to 12-31-97, about $380,000, Drying end Point Detection and Blending Detection, CAMP, Narabeth, PA

“CAMP - Consortium for the Advancement of Manufacturing in Pharmacy” 1-1-98 to 12-31-98, about $400,000, Blending Detection, Parametric Release, Crystallization, (PI or Co-PI) CAMP, Narabeth, PA.

“CAMP - Consortium for the Advancement of Manufacturing in Pharmacy” 1-1-99 to 12-31-99, about $467,000, Blending Detection, Parametric Release, Crystallization, Dye Lasers(PI or Co-PI) CAMP, Narabeth, PA.

NSF "Crystallization During Wet Granulation" ca. $30,000 7/1/97 – 12-31-01

NSF "Solid State Acid Base Reactions" ca. $35,000 7/1/97-12/31/00

"CAMP - Consortium for the Advancement of Manufacturing in Pharmacy" Founder of CAMP along with Professor C. Cooney, MIT, G.K. Raju, and W. Leishear. Funding for 1-1-99 to 12-31-07 about $450,000 per year. Projects include: Blending Detection, PAT, Crystallization.

"Effect of Water on the Stability of Solid Pharmaceuticals," Purdue-Wisconsin Joint Project. Founder along with Professor G. Zografi, University of Wisconsin. Program now includes Professors K. Morris, L. Taylor, R. Pinal, and T. Carvajal at Purdue and Professor N. Rodriguez-Hornedo, Univ. of Michigan. Current supporters are Pfizer, Boehringer, Bristol-Myers Squibb, Roche, Inhale, and Abbott. Funding for 1997-present, approximately $100,000 per year.

"Concretion," NSF, 1-1-00 to 12-31-02, $54,000.

"PTCC – Particle Technology and Crystallization Consortium" Founder of PTCC along with Professors A. Myerson, IIT, K. Morris, Purdue and C. Cooney, MIT. Funding for 1-1-03 to 12-31-07 about $400,000 total costs. Projects include: Crystallization monitoring, crystallization inhibition, PAT, and sensors.

"Discovering Once-a-Day Specialty Pharmaceutical Products" A.E. Mann Institute, Purdue University, 12-1-2008 to 5-31-2009, $98,150 DC.

"Mapping base technologies for detecting counterfeit medications" Lilly Endowment, Purdue University, $100,000, Jan. 1, 2008 through Dec. 31, 2010.

"Indiana Clinical Translational Institute," A. Shekhar, PI, Stephen Byrn, Program Leader Regulatory, 2% Effort, UL1RR025761, KL2RR025760, TL1RR025759, 5/1/08 to 4/30/13. Total Award $24,765,925.

"Drug Reformulation", Mann Institute, Purdue University, $265,000, 11/1/08 to 9/30/10.

"In-vitro, In-vivo Correlations for Dissolution Tests", FDA, $62,000, 9/1/09 to 9/30/10

Formulation of SMA Compound, DHHA-SAIC, August 2010 through July 31, 2011, ~ $180,000.

"Industrial Pharmacy Services Laboratory, IPPH Department, Purdue University, July 2012-present, about $200,000 per year

"Evaluation of Drug Product Formulations of Abuse Deterrent Drugs", NIPTE and FDA, HHSF2232013011189P, Sept. 16, 2013 – Sept. 12, 2015. Total Award $500,000.

"Master's Scholarships for Students Studying in Kilimanjaro School of Pharmacy for Purdue MS Degree, Merck Foundation, $600,000. Sept 2014 to June 30, 2016.

"Investigations of Active Coating End Point Determination", Astra Zeneca, Nov. 1, 2015 through April 30, 2016, $134,000.

"Evaluation of Drug Product Formulations of Abuse Deterrent Drugs", NIPTE and FDA, April 1, 2017 – August 31, 2017. Total Award $100,000.

"Pharmaceutical Quality Scorecard Development," NIPTE and FDA, 2U01FD004275, December 1, 2017 – November 30, 2018, $329,635 and Dec. 1, 2018 to March 31, 2020, $329,635.

"Methods of Evaluating Drug Abuse by Smoking," National Institute of Pharmaceutical Technology and Education/ FDA, 2U01FD004275, March 1, 2018, $94,000.

"Highly Bioavailable Compositions of URM-099," University of Rochester, May 1, 2018, $40,000.

"New Salts of Bedaquiline", S.R. Byrn, PI, Bill and Melinda Gates Foundation, June 1, 2020 to July 31, 2021, $180,000.

"Formulation Studies of Mitragynine", S. R. Byrn, PI, V. Gurvich and S. Hoag, Co-PI, Sept 30, 2020 to August 31, 2024, $695,000.

**Co-Principal Investigator on Grants:**

"Chemical-Antitumor Activity of Lactones and Epoxides," J.M. Cassady and S.R. Byrn, NIH Grant, #CA $114,906 Direct Costs, 9-1-75 to 8-31-78.

Member of the Cancer Center of Purdue University. This Cancer Center has received two core grants and a building grant from the National Cancer Institute. 1978 to 1994.

RR025759-61NIH/NCRR (A. Shekhar (PI), 07/01/08 - 06/30/13, Indiana Clinical and Translational Science Institute. Description: Multi-institutional project to support translational research in Indiana. Role: Program Leader, Regulatory Knowledge and Support, Member Pediatric Research Team. 2012 to present.

"Sustainable Medicines in Africa," Bill and Melinda Gates Foundation, July 1, 2018-June 30, 2020, $650,612.

"Sustainable Medicines for Africa", Merck Foundation, July 1, 2018 through June 30, 2020 – Two fellowship grants for $94,000, K. Clase, PI.

"NIPTE FDA Certification Program in Pharmaceutical Technology", Sept. 1, 2018 – Oct. 31, 2019, co-PI, $294,722, K Clase, PI.

"Amorphous Pharmaceutical Product Development using Containerless Methods." Oct 1, 2018-December 31, 2020. Phase 2 SBIR, Materials Development, Inc., Evanston, IL. $50,000.

"Assessment of Smoking and Vaping risk of opiods and commercial products, and standardization of methods to asses these properties" Sept. 1, 2019 to August 31, 2021, $226,993, Vadim Gurvich, PI, BAA, Contract No,. 5F40119C10112.

"Sustainable Medicines in Africa", S.R. Byrn Co-PI, Bill and Melinda Gates Foundation, August 1, 2018 to July 31, 2024, $1,700,000.

"Promoting Quality Medicines Plus", Task Orders 1 through 5, Co-PI, Technical Partner USP-USAID project, 1/1/2022 through 9/30/2023, $400,000.

"Quality Scorecard," FDA, BAA, Sept. 1, 2021 to Sept 30, 2023, $965,000.

**Consultantships and Companies Founded:**

Numerous consultantships with many pharmaceutical companies (including Novartis, Pfizer, BMS, J&J, Wyeth, Lilly, Roche, Abbott, Watson, and Merck) and many others over the years 1975 to present.

Co-Founder and Study Director, SSCI, a research and information GMP contract research firm in West Lafayette, IN employing about 90 people, 1991-2006. SSCI was sold to Aptuit in 2006. Consultant to Aptuit Nov. 2009-present

Consulting for several legal firms on major solid state chemistry, formulation, polymorphism, and salt litigations including the Zantac cases, the Paxil cases, the Norvasc cases, the Plavix cases, the Prevacid cases, the Elan nanoparticle patents 1990-present.

Co-Founder and Chief Scientific Officer (as a consultant), Improved Pharma, West Lafayette, Indiana, 2006 – present.

**Last Update:** May 2023

# EXHIBIT C

**Testimony in the Last Four Years**

**Stephen Byrn**

**January 4, 2023**

- *Intercept Pharms. v. Apotex Inc.*, No. 1-20-cv-01105 (D. Del.)
- *Impax Lab'ys, Inc. v. Actavis Lab'ys FL, Inc.*, No. 2-15-cv-06934 (D.N.J.)
- *Impax Lab'ys, Inc. v. Zydus Pharms. (USA), Inc.*, No. 2:17-cv-13476 (D.N.J.)
- *Biogen Int'l GmbH v. Mylan Pharms.*, No. 1:17-CV-00116 (D.W. Va.)
- *Biogen Int'l GmbH v. Amneal Pharms. LLC*, No. 1:17-cv-00823 (D. Del.)
- *In re Opana ER Antitrust Litig.*, No. 14 C 10150 (N.D. Ill.)
- *VIIV Healthcare Co. v. Gilead Scis.*, No. 1:18-cv-00224 (D. Del.)
- *Silvergate Pharms., Inc. vs Bionpharma, Inc.*, No. 18-cv-01962 (consolidated) (D. Del.)
- *In re Novartis and Par Antitrust Litigation*, No. 1:18-cv-04361-AKH (consolidated) (S.D.N.Y.)
- *Bayer Inc. v. Teva Canada Ltd.*, Court File Nos. T-1960-18, T-2093-18, T-435-19, T-806-19 (Federal Court of Canada)
- *Valeant Pharms. Int'l v. Actavis Lab'ys Fl, Inc.*, No. 1:18-cv-01288 (D. Del.)
- *Ferring B.V. v. Allergan, Inc.*, No. 12-cv-2650 (S.D.N.Y.)
- *Otsuka Pharm. Co. v. Zenara Pharma Private, LTD.*, No. 1-19-cv-1938 (D. Del.)
- *Intervet, Inc. v. Mileutis, Ltd.,* No. 3:15-cv-01371-RK-TJB (D.N.J.)
- *Intercept Pharms. v. Apotex, Inc.*, No. 20-cv-1105 (D. Del.)
- Israeli Patent Applications 249308 and 276948 in *Unipharm, Ltd. vs. Sierra Oncology, Inc.*, 2022

- *Neurocrine Biosciences v. Lupin Ltd.*, No. 21-cv-01042 (D. Del.)
- *Novartis Pharm. Corp. v. Lupin Inc.*, No. 21-cv-01105 (D. Del.)
- *Eyenovia, Inc. v. Sydnexis, Inc.*, No. IPR2022-00963, (P.T.A.B.)
- *Brigham and Women's Hospital, Inc. v. Perrigo Co.*, No. 1-13-cv-11640 (D. Mass.)